

LETTERS ON IMPLANT DENTISTRY

Short communications on basic research, clinical techniques and outcomes related to Neoss treatment solutions





Cover and this page:

Panoramic radiograph of the first patient treated with the Neoss implant system. The patient was treated in 2002 by surgeon Dr. Carl-Johan Ivanoff, receiving three implants in the posterior mandible (cover). In September 2017, fifteen years later, the patient received two more Neoss implants, this time in the posterior maxilla (this page) using instruments that are still fully compatible with the implants placed in 2002. Prosthetics: Dr. Ulf Palmqvist. Surgery: Prof. Christer Dahlin.

Innovation in practice

Since the introduction of the osseointegration technique for replacement of missing teeth more than 50 years ago, based on research from the groups around Professors Brånemark in Sweden and Schroeder in Switzerland, the market has been flooded by new dental implant systems and related products. Most of them have no scientific documentation to support their use, since this is generally not a legal requirement from the health authorities. Thus, it is up to each implant company to decide whether they think it is worth spending money on scientific studies. For two academicians like us, it is an obvious approach that any implant system or other product, which is going to be used in patients, should be scientifically scrutinized.

The Neoss implant system was invented by Mr Fredrik Engman and clinically developed and validated together with Professor Neil Meredith. They brought together a unique blend of basic and clinical science and dental implant engineering and put their combined knowledge and experiences into the design of the Neoss implant system. As a young engineer, Engman participated in the development of the original Brånemark system, which resulted in the clever characteristics that we take for granted today, such as self-tapping implants, double-threads and the use of implant drivers instead of fixture mounts. Meredith spent many years with research work on implant design and stability which, for instance, resulted in the introduction of the Resonance Frequency Analysis (RFA) technique for implant stability measurements. Hence, the design features of the Neoss implant system are there for a purpose; namely to facilitate placement, to ensure good stability and integration in all types of bone and to offer simple, safe and esthetic restorative options.

As with most products and product lines, the Neoss implant and portfolio has developed with time. The Neoss company recently introduced the NeoGen membrane for Guided Bone Regeneration (GBR) procedures, which also is based on a long scientific and clinical tradition within implant dentistry.

It is our great pleasure to present “Letters on Implant Dentistry”, which contains short communications related to Neoss treatment solutions. In here, the reader will find information regarding facts and rationales behind the Neoss implant designs. The bone tissue responses to Neoss implants in comparison with other implant brands are briefly discussed. Moreover, a systematic review on clinical studies using Neoss implants is presented. In addition, some papers present new developments and clinical outcomes with Neoss implants in different treatment situations. Finally, the reader will find papers related to GBR and the NeoGen barrier membrane.

Prof. Christer Dahlin

Prof. Lars Sennerby

Editors, Letters on Implant Dentistry

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Integration of Neoss ProActive implants in comparison with other brands of dental implants

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The present paper summarizes the experiences from an experimental rabbit model, which has been used by the research group to evaluate different brands of dental implants using removal torque measurements.

INTRODUCTION

Osseointegration is a biomechanical and biological treatment concept using bone-integrated fixtures to provide patients with anchorage for predictable long-term function of various types of dental and extra-oral prostheses and hearing aids. An implant obtains mechanical stability already at the time of placement surgery due to compression of the bone.¹

The level of primary stability is mainly determined by bone density but also drilling technique and implant design will have impact. The surgical trauma when preparing the osteotomy induces a repair process, which for a successful implant results in bone integration, i.e. new bone formation and remodeling at the bone-implant interface.²

Historically, osseointegration has been studied and evaluated in histological ground-sections where the bone-implant interface is studied by light microscopy.³ The bone response can be quantified by measurements of different parameters such as percentage of direct bone-implant contact (BIC) and bone fill inside the implant threads. However, the morphometric data do not say anything about implant stability. For this purpose, removal torque (RT) measurements in Ncm have been used in many animal studies, where threaded implants have been unscrewed until failure after different time points following placement

surgery.⁴ This technique measures the strength of the interface and is, for the same implant design, determined by the degree of direct bone contacts, type of bone (cortical vs cancellous) and maturation (time after surgery).⁵ It is anticipated that high degrees of BIC and RT indicate a stronger bone tissue response than low degrees of BIC and RT.

Research has shown that different surface topographies may result in different integration patterns⁶ and show different degrees of BIC and RT values.^{7,8} It is generally believed that moderately rough surfaces are superior to smooth surface topographies in this respect.⁹ Clinical studies have indicated higher survival rates for moderately rough implants compared to smooth ones¹⁰ and particularly in challenging situations such as in immediate/early loading¹¹ and bone augmentation protocols.¹²

Today, the majority of the commercially available implants have a surface texture as produced by different techniques such as blasting, acid etching, oxidation, coating and combinations of methods. This means that different brands also have different surface characteristics, which may well result in different bone tissue responses during healing.⁹

The first generation of Neoss implants were provided with a Bimodal surface, which was created by double blasting.¹³ This resulted in a surface topography with relatively

Brand	Implant	Dimensions	Surface	Number per time point
Straumann	BoneLevel RC SLActive	4.1 x 8 mm	SLActive: Sandblasted and acid etched	10
AstraTech	OsseoSpeed Implant	4.0 x 8 mm	OsseoSpeed: Grit blasted with TiO ₂ particles, fluoride modified	10
Zimmer	Tapered Screw-Vent Implant	3.7 x 8 mm	MTX: grit-blasted with a soluble medium	10
Implant Direct	ScrewPlant Implant	3.7 x 8 mm	SBM: Blasted with Soluble HA Particles	10
Osstem	GS II Fixture Implant	4.0 x 8.5 mm	RBM: Blasted with Soluble HA Particles	10
Nobel Biocare	Replace Select Tapered	4.3 x 10 mm	TiUnite: Oxidized	10
Neoss	ProActive Straight	4.0 x 11 mm	ProActive: Blasting with Ti particles, acid etching, chemically modified	10
Neoss	Bimodal Straight	4.0 x 11 mm	Bimodal: Double blasting with ZrO ₂ spheres and Ti particles	N/A

Table 1: Type of implants and surfaces used in the studies

low surface roughness. Although the overall clinical outcomes were good in the majority of cases, increased failure rates have been experienced in challenging cases such as GBR procedures and immediate/early loading protocols.^{13,14} Since 2009 the Neoss implants have a moderately rough ProActive surface, which is created by a combination of blasting and acid etching. The surface is hydrophilic due to electrowetting when in contact with fluids such as blood. Clinical data points to excellent outcomes also in GBR and immediate loading cases, which indicates a rapid and strong bone tissue response to ProActive implants.¹⁴⁻¹⁶

The purpose of this paper was to present removal torque data from a rabbit model used by the authors to evaluate different types of commercial dental implants.

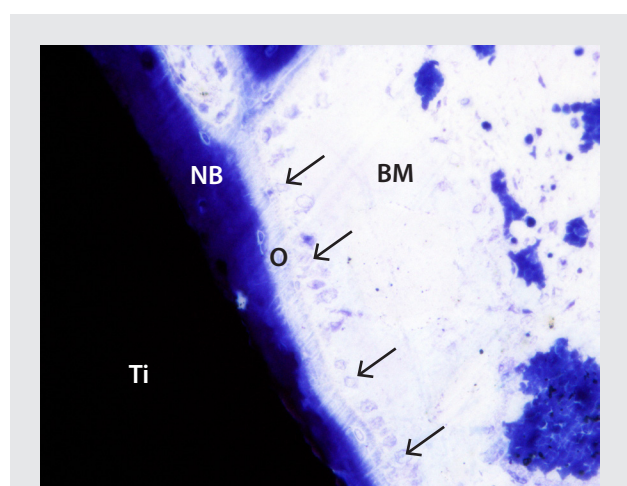


Figure 1: Light micrograph of the ProActive surface after 10 days of healing showing contact osteogenesis. New bone (NB) has been formed directly on the implant (Ti) surface. Active osteoblasts (arrows) followed by a layer osteoid (O) can be seen. BM = bone marrow.

MATERIALS & METHODS

The present research team have conducted a number of experimental studies to evaluate the integration and stability of various implant systems after different time points of healing.¹⁷⁻¹⁹ Data from three rabbit studies using removal torque measurements of in total eight implant types representing different geometries and surfaces (Table 1) were compiled in the present report. This rabbit model have been used extensively by many researchers and described in detail elsewhere. In brief, the implants had been surgically placed in the distal femoral condyles and proximal tibial metaphyses in adult rabbits. The implants had been used for histological ground-sectioning and subsequent histomorphometric analyses or subjected to removal torque measurements (Table 1).

A specially-designed rig consisting of an electrical torque transducer and a torsion rod was used for removal torque measurements. The rod was connected to the implant, an electric motor ramped the torque, which was registered and stored by a microprocessor. At the point of interfacial failure, the peak dropped and a slight rotational movement of the implant was observed. The peak torque was registered for each implant. A mean value was calculated for each implant type and time point. Only torque data from implant sites in the tibia were used for comparison.

RESULTS

Histological analyses showed bone integration by contact osteogenesis for both ProActive and Bimodal surfaces. This means that bone formation is induced directly on the implant surface and, consequently, bone forms from the surface and outwards (Figure 1).

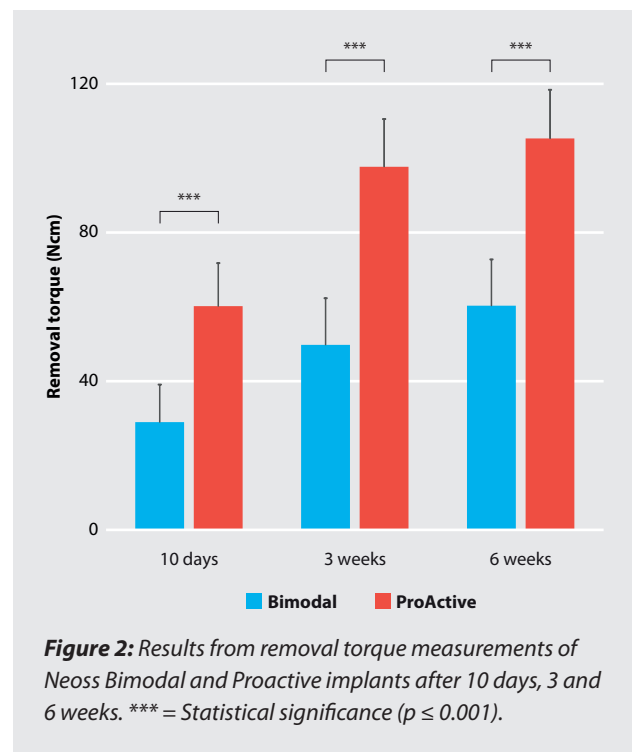
One study comparing 4.0 x 11 mm Neoss ProActive and Bimodal implants showed a marked and significantly higher RT for the ProActive surface after 10 days, 3 and 6 weeks after insertion (Figure 2). The ProActive surface reached the same stability already after 10 days as the Bimodal surface showed after 6 weeks.

Figure 3 shows the outcome of the removal torque tests of the various commercial brands of dental implants. It is obvious that the blasted and acid etched and hydrophilic implants (Neoss ProActive and Straumann SLActive) as well as oxidized implants (Nobel Biocare) showed higher torque values than the implants subjected to blasting with Ti- or HA-particles only (Osstem, AstraTech, Implant Direct).

Although no statistical test have been applied, the Neoss ProActive implant showed numerically higher RT values after three weeks when compared with the other brands. However, after six weeks both the Straumann SLActive and Nobel Biocare TiUnite surfaces showed similar high RT values as the Neoss ProActive surface.

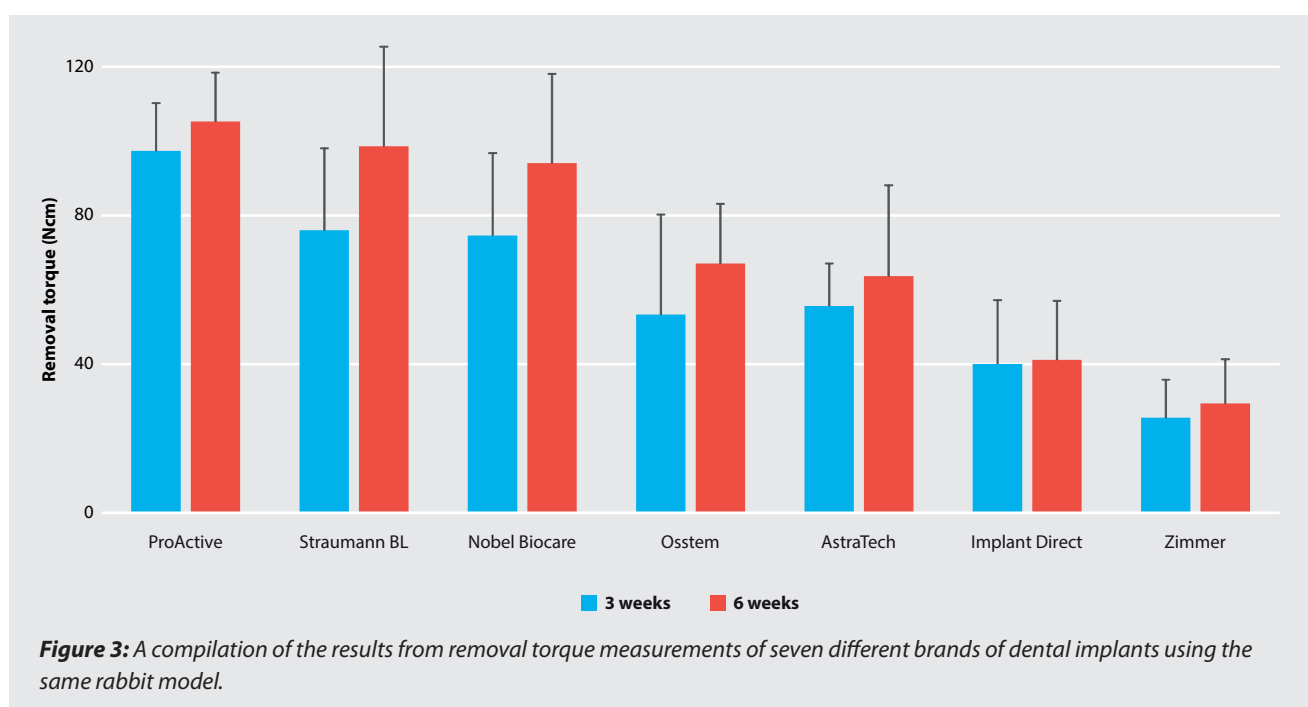
DISCUSSION

The removal torque test measures the strength of the bone-implant interface and the result depends on many factors, such as the anatomy of the implant site, time after placement, implant geometry and implant surface.¹ The test reflects how bone is interlocking with the implant surface as a result of bone formation and maturation. This is of particular importance in cases where short healing periods are used, since the implants will be subjected to rotational forces when attaching and loosening abutments, impres-



sion copings and prosthetic devices.

The implant types evaluated in this report represented different geometries (length, diameter, thread design) and surface characteristics (blasting, acid etching, oxidation), while the site anatomy and time factors were the same. It can be rightfully argued that the comparison of different diameters is unfair as, for instance, the implant radius has an impact on the outcome.²⁰ From a strict scientific point of view only one parameter at the time should be varied.



This can be done by changing the surface properties on identical implant designs,²¹ which was also the case when comparing ProActive and Bimodal surfaces.¹⁹ However, the experimental studies comparing different brands were performed in order to evaluate the actual implant types recommended by the manufacturers for routine clinical use. From this perspective, the Neoss ProActive surface showed the highest RT values followed by the Straumann SLActive and Nobel Biocare TiUnite surfaces, particularly after 3 weeks of healing. However, since no statistical tests were applied due to the design of this report, it is not known if the differences were significant.

It is concluded that the Neoss ProActive surface provokes a rapid and strong bone tissue response after surgical placement, which results in high resistance to torque after 10 days, 3 and 6 weeks of healing in a rabbit model. In this respect, the Neoss ProActive surface performs better or similar as other brands of dental implants.

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The technology behind the solid-state hydrated ProActive surface

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This article describes the techniques applied on a relatively smooth surface to enhance early healing response while still assuring predictable long term clinical success. In particular, it describes how a superhydrophilic surface can be achieved using a completely unique and novel method to deposit hydrated ions onto an implant surface, effectively creating a solid-state water surface.

INTRODUCTION

The biological behavior and clinical performance of a dental implant is dependent on the correlation between implant design, drilling protocol and implant surface properties. The key to a successful implant treatment is mechanical stability (primary stability) until the healing process has established the osseointegration (secondary stability) in order to minimize the stability dip normally occurs after 2-4 weeks of healing (Figure 1).

Implant design and drilling protocol mainly influence

the primary stability, whereas the implant surface properties mainly influence the secondary stability. All three properties can be optimized such that the primary stability can be retained for a longer period and secondary stability can be achieved faster. This way, the dip in combined stability can be minimized or even eliminated.

SURFACE PROPERTIES AND OSSEOINTEGRATION

Surface roughness

The introduction of moderately rough modified implant surfaces improved the clinical success in implant dentistry compared to the original machined surface.

There are several underlying factors in why clinical advantages are seen. The modified surfaces are normally sharper and mechanically create a higher friction and retention than a machined surface, thus increasing the primary stability. There is also evidence that these sharp features create bone debris as the implant is inserted and the debris acts as a nucleus for new bone formation.¹ Furthermore, if the surface has varying roughness and/or machined features such as grooves, the debris can be collected and the remodeling can be even further enhanced. There is also evidence that cells have an increased affinity to topographic features such as grooves and ridges if they are roughly the same size or slightly smaller than the cells. These factors result in osteoconductive properties of the surface, meaning that bone cells are in direct contact with

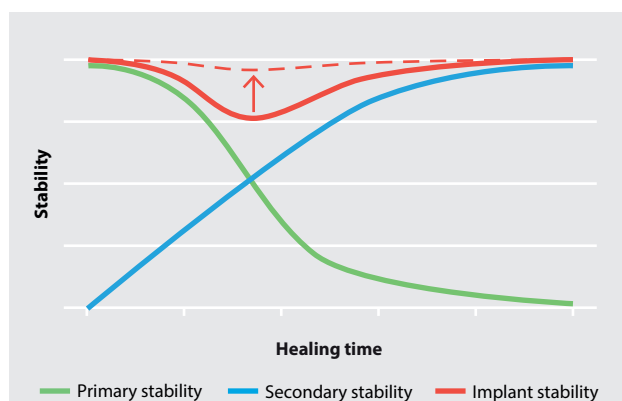


Figure 1: Mechanical stability of a dental implant after insertion. A dip in implant stability generally occurs after 2-4 weeks when the remodeling weakens the initial stability and the osseointegration is not fully developed.

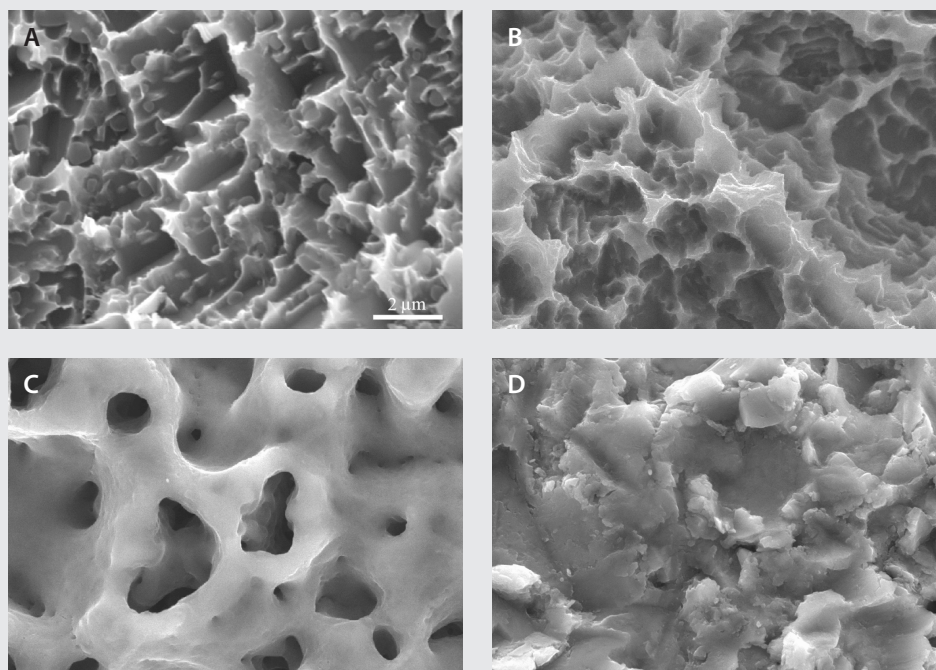


Figure 2: SEM images of a number of commercially available dental implant surfaces:

(A) ProActive, Neoss
(B) SLActive, Straumann,
(C) TiUnite, Nobel Biocare,
(D) TiOblast, Dentsply Implants.

and can develop from the implant surface.²

Excessive surface roughness may increase the likelihood of certain risks as it can be more prone for contamination and more difficult to clean. This could be one reason why there has been increased reporting of infection-related issues around dental implants in recent years and where a correlation to the rough surface has been shown.³ An excessively rough surface can also lead to release of wear particles and crack initiation leading to mechanical failures.

Hydrophilicity

The importance of implant surface cleanliness has been recognized for a long time. In recent years, the significance of hydrophilic properties to enhance the early biological healing process has been highlighted. A prerequisite for achieving a hydrophilic surface is that the underlying surface is ultraclean with minimal carbon content. Manufacturing, storage, packaging and handling all contribute to surface contamination of a dental implant. Carbon adsorption reduces surface energy and wettability, thereby impairing healing and bone formation.

Maintaining the hydrophilicity from time of manufacture to clinical use normally requires the implant to be immersed in a liquid as part of the packaging. This leads to more complex packaging containers and additional costs.

THE PROACTIVE SURFACE

The ProActive surface was developed 10 years ago. It is characterized by a dual surface roughness to optimize bi-

ological functions: The collar has a surface roughness with an Sa-value comparable to a polished surface (0.2-0.4 µm), while the micro- and macro-roughened threaded portion have an Sa-value around 1 µm. This addresses the need both to provide an osteoconductive surface during healing and to minimize bacteria adhesion in regions where the implant can be exposed to the oral environment after long term function.

Through a series of processes, an osteoconductive and superhydrophilic implant surface with different roughnesses on collar and threads is formed.

The ProActive surface is manufactured using the following steps:

- Blasting - to create the surface macro-roughness
- Etching - to create the surface micro-roughness
- Treatment with hydrated magnesium ions to make the surface superhydrophilic.

Parameter	Sa (µm)	Sdr (%)
ProActive	Collar: 0.3-0.4 Thread: 0.8-1.0	Collar: 50 Thread: 103
SLActive	1.75	143
TiUnite	1.1	37
OsseoSpeed	1.4	37

Table 1: Surface roughness – a comparison of Sa and Sdr values for a number of commercially available dental implant surfaces: (A) ProActive, Neoss, (B) SLActive, Straumann, (C) TiUnite, Nobel Biocare, (D) Osseospeed, Dentsply Implants.

Blasting - creating the macro-roughness

After machining and cleaning, the Neoss ProActive implant threads are carefully blasted with a process that leaves no chemical residue on the surface and creates a macro-roughness while maintaining the self-cutting features of the implant. The collar is not blasted, resulting in the dual surface roughness.

Etching - creating the micro-roughness

After blasting, the complete implant – thread and collar – is etched to receive a superimposed micro-roughened surface. At this point the actual Neoss ProActive surface has been created.

The ProActive etching process generates a honeycomb micro structure with fine ridges and small pits at sub-micron level. Compared to other implant surfaces, the ProActive micro morphology structure is similar to SLActive (Straumann) while completely different to TiUnite (Nobel Biocare) and OsseoSpeed (Dentsply Sirona Implants) as demonstrated by SEM (Figure 2).

The ProActive surface has been designed with lower surface roughness than most competitor surfaces (Table 1).⁴ The design rationale behind the lower roughness is to achieve a balance between initial stability and long-term predictability without having the attraction of bacteria that rougher surfaces can exhibit.³ Once a machined surface has integrated, the long-term success is high. The issue is the failure rate during the first year.⁵ The ProActive implant design, in combination with the drilling protocol, creates a high and predictable initial stability that allows for a slightly smoother surface with micro pits and still provides predictable means for fast and strong healing. This is shown in animal models in comparison with other implant surfaces² as well as in a vast number of clinical studies.⁶

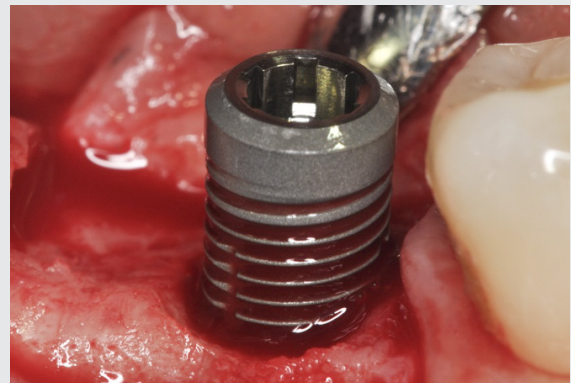


Figure 3: Surgical placement of a ProActive implant visually demonstrating the hydrophilic properties through the blood wicking up the threads. The shiny implant collar is typical for the hydrated surface.

Superhydrophilicity treatment

After etching, the implants are subjected to the superhydrophilicity treatment which enables the implant to achieve an exceptionally high level of wettability without altering the blasted and etched surface.

A thin layer of ultra-clean hydrated Mg^{2+} (magnesium) ions is deposited onto the surface. A hydrated Mg^{2+} ion is an Mg^{2+} ion that binds six water molecules. The hydrated ions create bonds with each other and the implant surface to form a stable, solid-state, water-rich film on the implant. The film has a solid, transparent and glossy appearance similar to ice and is stable on the implant surface at temperatures as high as 60°C.

This treatment is what makes the ProActive surface superhydrophilic, as demonstrated in surgical practice (Figure 3) and by the immeasurable low contact angle compared to other dental implant surfaces (Figure 4).

The Mg^{2+} ions used in the superhydrophilicity treat-

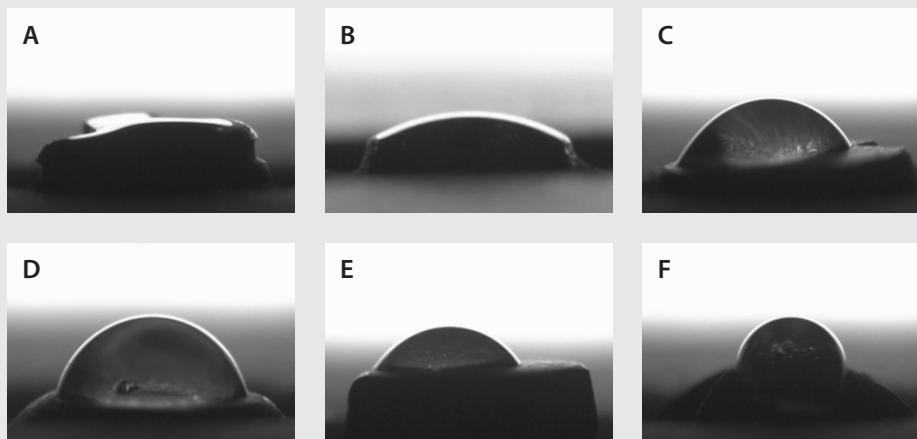


Figure 4: Hydrophilic properties were examined by a simple drop test on different dental implant surfaces: (A) ProActive, Neoss, (B) SLActive, Straumann, (C) TiUnite, Nobel Biocare, (D) Osseospeed, Dentsply Implants, (E) Bimodal, Neoss, (F) Ankylos Plus, Dentsply Implants.

Surface	Elements, in atomic %																
ProActive as delivered (following the super hydrophilicity treatment)	Ti	O	C	B	P	S	Ca	Cl	Si	Cu	K	Na	F	Fe	Al	Pb	Mg
	3.2	19.0	4.7	0	0.3	0	0.4	10.8	0	0	0	0	0	0	0	0	61.6
ProActive as implanted (after rinsing)	Ti	O	C	B	P	S	Ca	Cl	Si	Cu	K	Na	F	Fe	Al	Pb	Mg
	22.2	56.7	19.1	0	0.8	0	0.3	0.6	0.5	0	0	0	0	0	0	0	0

Table 2: Surface chemistry ProActive. As delivered the ProActive surface main constituent is Mg^{2+} ions. Upon being exposed to a wet environment the hydrophilic process is activated leaving a completely clean surface with minimal residues.

ment are highly soluble which means that there is no Mg^{2+} bound to the implant surface once the implant is implanted. Mg^{2+} is abundant in the human body. It has also been shown to be an important substance for bone formation,⁷ but any direct correlation for ProActive still needs to be explored.

Even though the deposited water and Mg^{2+} ions are highly soluble, they are highly stable on the surface which enables the implants to be delivered in conventional packages. This eliminates the need for the implant to be packaged in a liquid solution like other hydrophilic implants.

The ProActive production process uses non-contaminating blasting particles and an ultra-clean water supply. In addition, the implant packages are made of glass. This maintains the low carbon content on the implant surface, thereby maximizing surface energy.

Compared to other dental implant surfaces with carbon levels in the 30-50% range,⁸ the levels of surface contamination on the ProActive surface is very low with carbon levels generally below 20% and minimal levels of the trace elements P, S, Ca and Cl (Table 2).⁹ The data also shows that the ProActive superhydrophilicity treatment does not leave any Mg^{2+} remnants.

CONCLUSION

By applying a superhydrophilicity treatment to a carefully designed implant geometry and implant surface, the ProActive implants offer high initial stability and allow for predictable and safe use in challenging indications such as immediate loading and in compromised bone, and for patients with poor hygiene or pathological issues.

It is also suggested that the dip in stability during the remodeling process between initial stability and osseointegration, an effect seen for all well researched implant systems of today, is minimized with the ProActive implants.¹⁰ One reason for this can be the ability of the implant body to achieve high initial stability in combination with the very potent surface that enhances early bone formation, thus considerably minimizing or in some cases even eliminating the crucial and sensitive time where the initial

stability is declining before the osseointegration is fully in place (Figure 1).

It is clear that an implant with a surface roughness on the lower end of the scale for moderately rough implants (1-2 μm), in combination with an implant design that achieves high initial stability, can perform very well also in challenging indications.

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Implant survival, bone remodeling and implant stability of Neoss implants: a systematic review of the literature

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This systematic review of the published literature on Neoss dental implants shows minimal bone resorption (average 0.6 mm after 5 years), high implant survival (CSR 96.8% after 5 years) and excellent primary and secondary stability in all types of bone.

INTRODUCTION

There are hundreds of different implant systems available on the market worldwide. The preference for one system over another could be based on anything from scientific evidence, clinical handling, inventory, and cost to preference of referring dentists.

However, the clinical safety and performance remains the only factor that ultimately defines the clinical suitability of an implant system.

The aim of this systematic review is to assess the current scientific evidence on Neoss dental implants regarding implant survival, bone remodeling and implant stability.

MATERIALS AND METHODS

A bibliographical electronic research was carried out using PubMed/Medline and Google Scholar, identifying all published articles that report on clinical follow-up data on Neoss dental implants.

Electronic database searches were conducted in August 2017 and included all available data up to that point. The search term for the PubMed/MedLine search was “neoss OR ((proactive OR bimodal) AND dental implant)”. For the Google Scholar search, the search term “neoss implant” was used. No restrictions were applied to the electronic searches. In addition to the online sources, the content of the Neoss internal literature database was screened.

To be eligible for further analysis, the publications should report at least one-year clinical follow-up data on Neoss implants. Studies with shorter follow-up were included in the initial stability assessment if ISQ data was available.

The following exclusion criteria applied: less than 10 patients followed; no separate reporting on Neoss implants; technique descriptions; case reports; review articles; language not English.

RESULTS

The search yielded 430 articles. After the elimination of duplicates and the screening of titles and abstracts, full texts were retrieved for 142 articles for further evaluation. Twenty-two articles met the inclusion criteria and were included in the overall data analysis.¹⁻²² Seventeen articles were included in the implant stability analysis.^{4-8,10-12,15-18,20-24}

The analyzed articles (Table 1) present the combined clinical outcome of more than 2350 Neoss implants in more than 830 patients, studied in 18 independent clinical studies with a follow-up time of 1 to 6 years. The combined data covers all major indications and treatment protocols.

Implant survival

The combined CSR in the identified literature was 97.4% after 1 year and 96.8% after 5 years. The CSR for Bimodal

Study	Study type	Topic	Implant type	Follow-up time	Sub-groups	No. of patients	No. of implants	Survival rate (CSR)	Bone loss (mm)
Zumstein 2012 ¹ Zumstein 2008 ²	Retrospective controlled	GBR vs. non-GBR	Bimodal, Straight	4-5 years		50	183	95.0%	0.4
					Non-GBR	-	57	98.2%	-
					GBR	-	126	93.5%	-
Sennerby 2016 ³ Degasperi 2012 ⁴	Retrospective case series	Long-term follow-up on ProActive	ProActive, Straight	60 months		49	102	99%	0.8
Sennerby 2016 ^{5 *}	Retrospective case series	Immediate placement, early loading, full-arch	ProActive, Straight, Tapered	1-6 years		43	258	96.5%	-
Andersson 2015 ^{6 *}	Retrospective controlled	Immediate placement, early loading, full-arch	Bimodal, ProActive, Straight	1-6 years		50	284	93.7%	0.8
					Bimodal	-	116	89.7%	-
					ProActive	-	168	96.4%	-
Acham 2017 ⁷	Randomized controlled trial	Overdenture on Locators	ProActive	3 years		20	80	100%	-
Vanden Bogaerde 2016 ⁸	Randomized controlled trial	Early implant stability	Bimodal, ProActive, Straight	3 years		11	22	95.5%	-
					Bimodal	11	11	100%	0.4
					ProActive	11	11	90.9%	0.6
Dahlin 2013 ⁹	Prospective case series	Multi-center	Bimodal, Straight	1 year		177	590	97.8%	0.6
Becker 2013 ¹⁰	Prospective case series	One-stage, delayed load	Bimodal, Straight	14 months		76	100	93%	0.6
Sennerby 2012 ¹¹	Prospective case series	Two-stage surgery	Bimodal, Straight	1 year		90	218	98.6%	0.6
Zwaan 2016 ¹²	Retrospective case series	Tapered implants	ProActive, Tapered	1 year		97	163	96.9%	0.52
Aktas 2015 ¹³ Aktas 2014 ¹⁴	Retrospective case series	Bar-retained overdenture on 4 implants	Not reported	3 years		10	52	100%	-
Vanden Bogaerde 2010 ¹⁵	Prospective case series	Immediate loading	Bimodal, Straight	18 months		21	69	98.5%	0.7
Zumstein 2016 ¹⁶	Retrospective controlled	GBR vs. non-GBR	ProActive, Straight	1 year		50	159	98.7%	0.7
					Non-GBR	-	67	98.5%	-
					GBR	-	92	98.9%	-
Di Lallo 2014 ¹⁷	Prospective controlled	Sinus lift	ProActive, Straight	1 year		25	38	100%	-
Alsabeeha 2011 ¹⁸	Randomized controlled trial	Overdenture on single implant	Bimodal, Straight	1 year		12	12	100%	0.23
Wiesner 2010 ¹⁹	Randomized controlled trial	Connective tissue grafts	Bimodal, Straight	1 year		10	20	100%	0.7
Andersson 2008 ²⁰	Retrospective case series	Two-stage surgery	Bimodal, Straight	1 year		44	102	98.1%	0.7
Volpe 2013 ²¹	Retrospective case series	Sinus lift, osteotome method	Bimodal, Straight	16 months		20	29	100%	0.7
Pagliani 2012 ²²	Prospective case series	Bone grafting	Bimodal, Straight	1 year		19	34	97.1%	0.5

Table 1: Summary of identified data. * Some implants in the Andersson data⁶ are also part of the Sennerby data⁵.

implants was 97.0% after 1 year and 96.0% after 5 years. The overall CSR for ProActive implants was 97.8% after 1 year and 97.5% after 5 years (Figure 1).

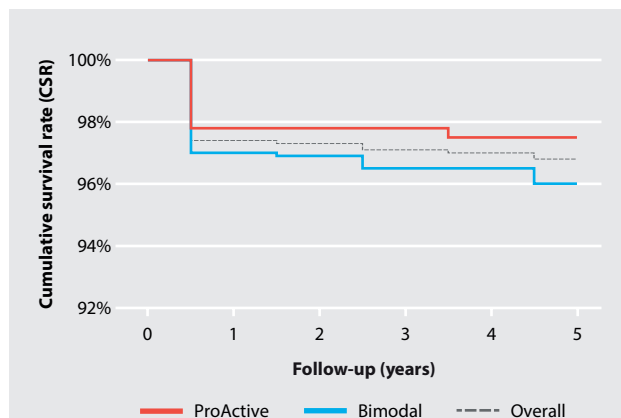


Figure 1: Overall cumulative survival rates for Neoss Bimodal and ProActive implants. Compilation of all published studies on Neoss implants that report implant survival data (n=19).

Bone remodeling

The weighted mean bone loss in all studies was 0.62 mm after 1 year, and 0.60 mm after 5 years (Figure 2). No differences in bone loss were seen between Bimodal implants and ProActive implants (0.58 mm vs. 0.62 mm after 1 year).

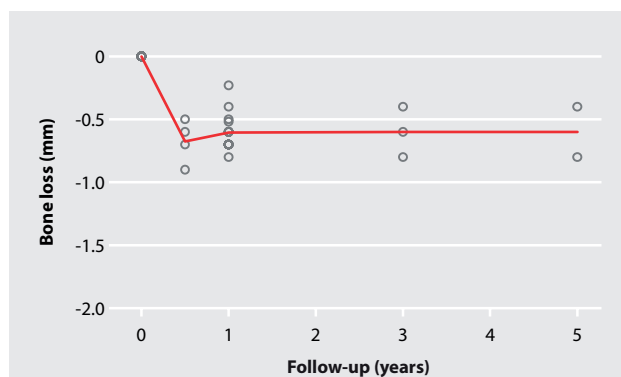


Figure 2: Mean marginal bone remodeling. Compilation of all published studies on Neoss implants that report bone remodeling data (n=15). Each circle represent one study, the line represents the mean of all studies.

Implant stability

The weighted mean ISQ at time of implant insertion in all studies was 73.1 (range 68.1 – 76.7). The mean insertion ISQ of each included study is shown in Figure 3. No differences in RFA at insertion were seen between Bimodal implants and ProActive implants (mean 73.1 vs. 73.1).

DISCUSSION

Implant survival

The combined CSR in the identified literature was 96.8% after 5 years. The identified studies contain normal day-to-day use as well as more demanding treatments such as guided bone regeneration (GBR), immediate loading after total tooth extraction, and sinus lift procedures. The diversity of included studies therefore reflects the clinical reality of implant use. The CSR of Neoss implants (97.4% after 1 year and 96.8% after 5 years) compares well with systematic long-term data which showed 94.6% CSR.²⁵ Neoss data is mostly short-term (1 year) but it is established that the vast majority of implant losses occur during the first year. Therefore one-year data is usually a good estimation of longer term success. The long-term studies show high survival rates after the first year further supporting the long-term success of the Neoss implant system.^{1,3,5-8,13}

Bimodal implants account for a higher percentage of

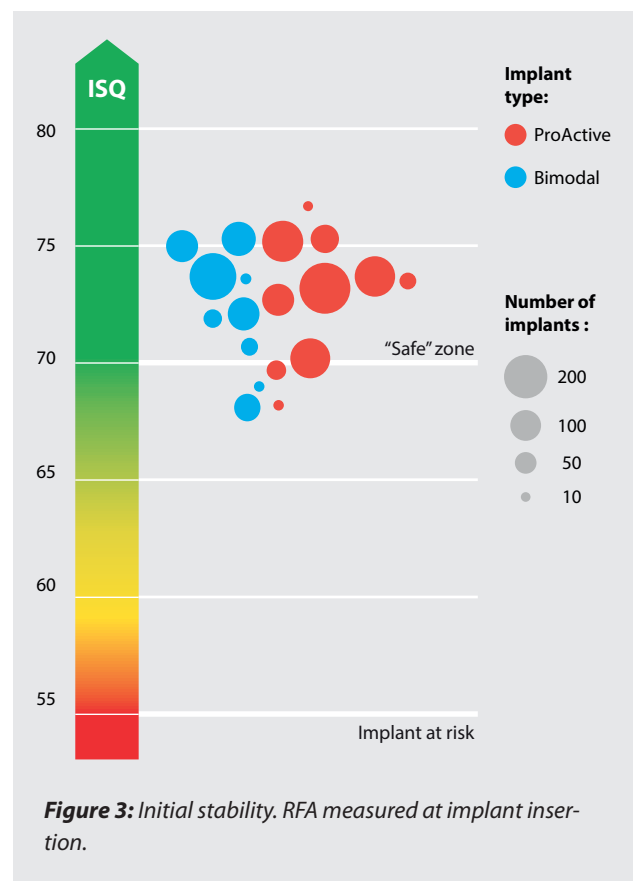


Figure 3: Initial stability. RFA measured at implant insertion.

the implant losses. The cumulative survival rates after 5 years were 96.0% for Bimodal implants and 97.5% for ProActive implants (Figure 1). The lower survival rate for Bimodal implants could be explained by lower survival rates in difficult cases. Zumstein et al. showed that Bimodal im-

plants had a tendency of lower survival rate in GBR sites (93.5%) than in non-augmented bone (98.2%).^{1,2} When the same research group repeated the same study setup with ProActive implants, no difference was seen between GBR (98.6%) and non-GBR sites (98.9%).¹⁶ Andersson et al. studied immediate loading of full arch reconstructions after total tooth extraction. They found that the survival rate for this difficult treatment modality was less successful using Bimodal implants (89.7%) than with ProActive implants (96.4%).⁶ Hence, the present data indicate that the successful usage of Bimodal implants is further improved by the ProActive surface which enables more predictable treatment outcomes in difficult cases.

Bone remodeling

The weighted mean bone loss in all studies was 0.62 mm after 1 year, and 0.6 mm after 5 years. This implies very stable bone levels after minimal bone remodeling during the first year (Figure 2).

The data indicate less bone loss for the Neoss implant system than what is shown in a systematic long-term review of multiple implant systems by Moraschini et al., which reported a mean bone loss of 1.3 mm,²⁵ and also less than what is shown in a systematic review of the TiUnite implant surface (mean 0.9 mm after 5 years).²⁶

It has little clinical implication if the bone level around an implant is 0.3 mm or 0.9 mm. However, the mean value is interesting because it indicates if there is a high percentage of cases that have lost a lot of bone. High percentage of cases with bone loss more than 2 or 3 mm will result in a higher mean bone loss value and higher standard deviations.

Derks et al. studied the prevalence of peri-implantitis in a Swedish population. From the national implant data register, 900 randomly selected patients treated with implants 9 years earlier were invited to a free-of-cost examination. Implants were Straumann (32.6%), Nobel Biocare (39.4%), Astratech (18.4%) or other brands (9.4%). Derks et al. found that 9.9% (157 of 1578) of all implants had lost more than 2 mm bone from baseline to 9 years and that 4.9% (78 of 1578) had lost more than 3 mm.²⁷

In the studies that report frequency data on bone loss on Neoss implants, 5.1% (46 of 894) have lost more than 2 mm and 1.1% (10 of 894) have lost more than 3 mm after 1 year. After 5 years, 5.1% (7 of 136 implant) have lost more than 2 mm and 0.7% (1 of 136) more than 3 mm.^{1,3,4,9,11,12,15,16}

Compared to Derks et al., the percentage of Neoss implants with more than 2 mm bone loss is nearly halved (5.1% vs. 9.9%). This indicates that Neoss implants have a lower percentage of high bone loss cases than the main

competitor implants. Since peri-implant bone loss is one of the prerequisites for peri-implantitis, low incidence of bone loss means low incidence of peri-implantitis.

One can argue that the Derks data is over a longer follow up (9 years vs. 5 years), but the bone levels are usually relatively stable after the first year. It should also be noted that the Derks data might underestimate the amount of bone loss in their study since they accepted radiographs as late as 2 years after surgery as baseline radiographs and therefore any bone loss that occurred before the baseline radiograph is not taken into account.

Implant stability

The state of the art knowledge defines ISQ > 70 as high implant stability. This is a level that enables immediate and early loading of single tooth reconstructions.²⁸ The weighted mean insertion ISQ in all studies was 73.1, with all but three studies having an average ISQ > 70 (Figure 3). It can therefore be concluded that high initial implant stability is generally achieved with the Neoss implant system.

The available data suggests that the primary stability is generally maintained or even increased during the first year after implant placement. All available data points are plotted in Figure 4 and a trend of increasing stability over time during the first year is clearly seen.

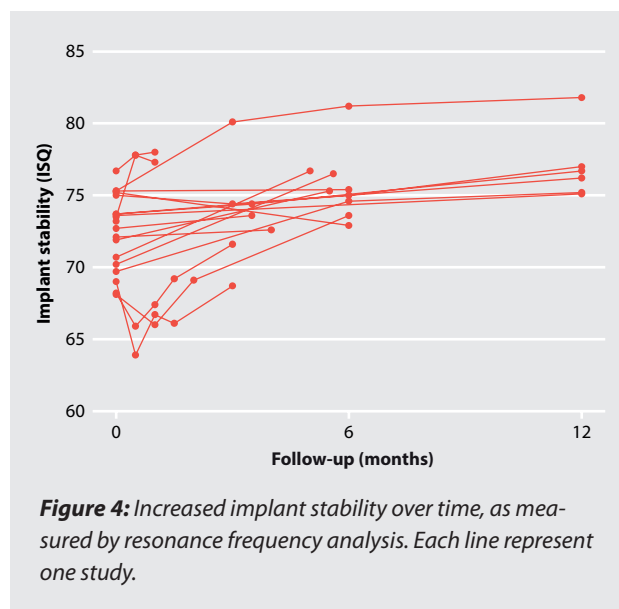


Figure 4: Increased implant stability over time, as measured by resonance frequency analysis. Each line represent one study.

No difference in initial stability was seen between Bimodal and ProActive implants. However, a comparative study by Vanden Bogaerde et al. showed that ProActive implants maintain significantly higher stability during the healing phase than Bimodal implants.⁸

CONCLUSION

This systematic review of the published literature on Neoss dental implants shows minimal bone resorption (average 0.6 mm after 5 years), high implant survival (CSR 96.8% after 5 years) and excellent primary and secondary stability in all types of bone. The data also shows that the ProActive surface has increased secondary stability and increased clinical success in difficult cases compared to the Bimodal surface.

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Computer-guided implant surgery using Neoss guide kit: Clinical report of a severely atrophic osteoporotic patient

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A guided surgery technique for prosthetic rehabilitation of a severely atrophic osteoporotic patient using Neoss implants is described in this clinical report.

INTRODUCTION

During the past years, technological progress of interactive software for three-dimensional (3D) reconstruction of computed-tomography (CT) scans has facilitated treatment of dental implant patients.^{1,2} Computer-software planning is used to predictably perform implant placement in partially edentulous as well as fully edentulous cases involving a single arch or both arches.

The computer-guided implant placement approach has numerous advantages. The pre-surgical planning and surgery is more focused on the prosthetic aspect and emphasizes the team approach of the prosthodontist, surgeon, and dental laboratory. The surgeon can place the implants more accurately, predictably, and safely, in the optimal positions as planned in the virtual software. In addition, vital structures, such as adjacent tooth roots and the inferior alveolar nerve, can be carefully assessed and avoided. Another important advantage offered by this type of technique is represented by placing implants in minimal amounts of available bone, including patients that would traditionally require bone grafting.³

Guided surgery is often performed using a minimally invasive approach without raising a flap, thereby minimizing postoperative pain, swelling and recovery time.⁴⁻⁷

However, guided surgery is not free from errors, and the operator has to be proficient in the use of this procedure. Moreover, the operator has to follow strict protocols in order to overcome any difficulties and reach treatment success.

A recent systematic review on computer guided implant surgery revealed a high cumulative survival rate (CSR), 97.2% with a low marginal bone loss (1.45 mm) during 4 years of follow-up.⁸

The aim of this clinical report is to describe a guided surgery technique for Neoss implants using the Neoss guide kit. The rehabilitation of a 70-year-old woman with a severely atrophic maxilla is presented.

TECHNIQUE DESCRIPTION AND CLINICAL REPORT

Patient history

A 70-year-old female presented with a dental abscess in the upper jaw and an unsatisfactory lower denture. Her medical conditions included multiple sclerosis, hypertension and osteoporosis. The osteoporosis was treated by oral bisphosphonate (alendronic acid once a week for the last 6 years). A panoramic x-ray was taken and showed the presence of mobile grade II and III teeth in the upper jaw and a severe bone resorption of the mandible (Figure 1). The



Figure 1: Panoramic radiograph showing the pretreatment clinical situation: Mobile hopeless teeth in the maxillary arch supporting a removable prosthesis. Dramatic bone resorption in the mandible caused by the use of a removable denture for more than 20 years.

maxillary teeth were all extracted and a provisional full denture was provided to the patient and frequently relined.

CT scan

After six months of healing, computed tomography (CT) scanning of both arches was performed using the double scanning technique. The first CT was taken with the patient wearing two new relined radiolucent prostheses with gutta-percha fiducial markers and a radiological silicon index for the occlusion (Figure 2). The second CT was taken of the denture replica alone. This scan was taken to get a higher quality digitization of the denture because of the

similarity in radiodensity of the denture and the soft tissue. The two CT scans were transferred into the surgical planning software (NobelClinician Software, Nobel Biocare) and matched using the fiducial markers.

Digital planning

The 3D planning was performed using the planning software. The implant positions were optimized in accordance with the anatomical structures as well as the prosthetic references. In the maxilla it was possible to virtually plan six Neoss ProActive Tapered 13 mm implants parallel to each other in order to facilitate the application of the pre-fab-

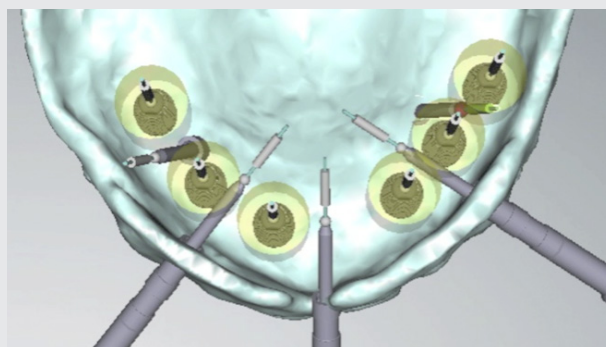
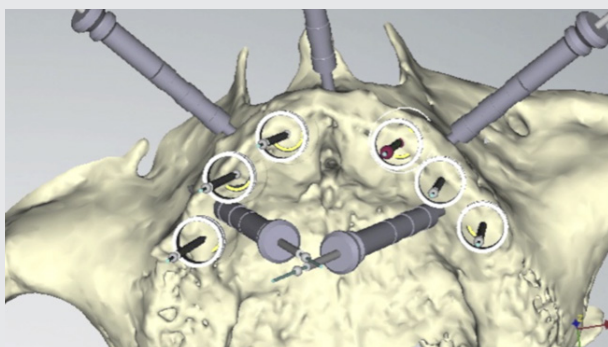
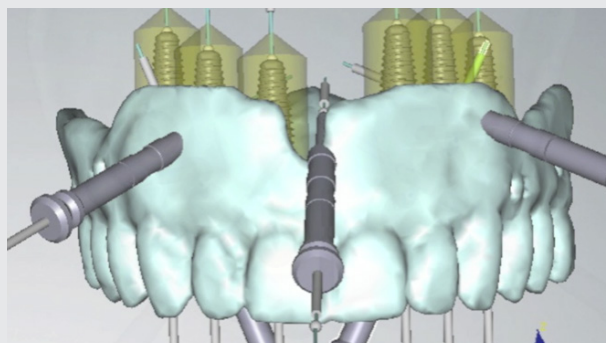


Figure 2: Six months after extraction of remaining teeth, the patient underwent CT examination with a double scanning technique wearing a radiological template. Six parallel Neoss Tapered implants were virtually planned according to the prosthetic plan.



Figure 3: Image of the surgical template produced by a CAD-CAM stereolithographic procedure. A model cast was obtained before surgery by inserting implant replicas through the surgical template. A prefabricated provisional prosthesis was obtained by soldering a titanium bar onto the temporary abutments, and a Toronto-bridge was produced by re-adapting the patient denture.

ricated prosthesis (Figure 2). Three anchor pins were planned buccally and two crossing palatal anchor pins were planned to prevent surgical template bending movements during surgery (Figure 2). In the atrophic mandible, virtual planning was performed, followed by a standard non-guided open flap procedure to place four 7 mm implants.

Laboratory work

Based on the digital planning, a surgical template and laboratory products were ordered. The dental technician fabricated a cast model using the surgical template to achieve accurate implant positions according to the digital planning. Implant mounts were attached to the surgical template, and implant replicas were connected to the implant mounts. This way, the implant replicas were correctly placed into the cast model. A rigid framework was then easily created by soldering a bar on six temporary abutments connected to the cast model. The framework was adapted inside the old provisional denture. The flanges and the palatal portion of the denture were removed, transforming the denture into a rigid metal-reinforced fixed provisional prosthesis ready to be installed immediately after implant insertion (Figure 3).

Patient preparation

On the day of surgery, preoperative antibiotics (Amoxicillin 2 g) were given orally 1 hour prior to the surgery and were continued for another 5 days postoperatively. Intravenous sedation (Midazolam 5mg/5ml) and local anesthetic (2% lidocaine on 1:80.000 of adrenalin) was administered.

Surgical procedure

The surgical template was secured intraorally using the anchor pins. A tissue punch was used to remove the gingiva from the alveolar bone through each guide sleeve.

A strict drilling protocol was followed. The implants osteotomies were prepared using a series of guide keys with different diameters that completely coincide with the series of twist drills (Figure 4). The osteotomies were prepared in order to gain a minimum insertion torque of 35 Ncm.

Once the osteotomies were prepared, six Neoss ProActive Tapered 4.5 x 13 mm implants were placed through the surgical template and secured by means of dedicated Neoss guided implant mounts. At the end of the surgery the mounts, the anchor pins and the surgical template were removed (Figure 4). Implant stability (ISQ, Osstell Mentor) was measured and the prefabricated prosthesis was screwed onto the implants and endo-oral radiographs were taken to check the fit of the prosthesis (Figure 5).

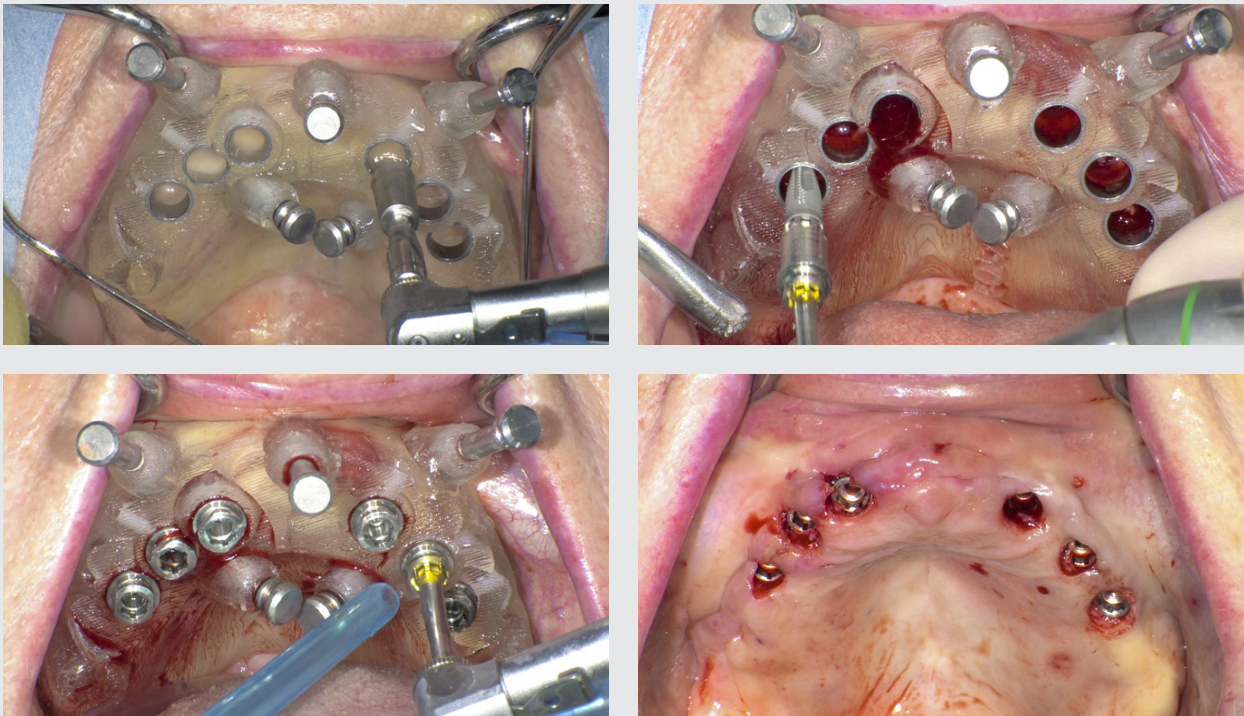


Figure 4: Surgical procedure : intraoral stabilization of the surgical template by means of three buccal and two crossing palatal pins, removal of soft tissue by circular guided mucotome. After drilling sequences, tapered Neoss implants were inserted through the guide. The surgical template was removed at the end of the surgery showing the results of flapless insertion.



Figure 5: The prefabricated provisional prosthesis was screwed onto the implants after surgery. Occlusal check with the lower denture inserted into the mouth and radiological control of the fit of the prosthesis.

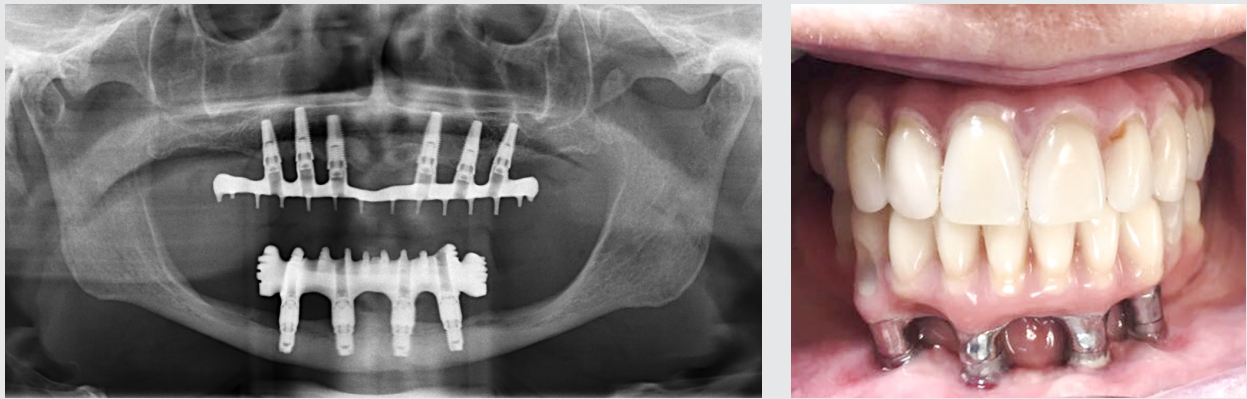


Figure 6: Panoramic radiograph and clinical situation three years after the delivery of the maxillary CAD/CAM titanium-resin definitive bridge.

Definitive prosthesis delivery

Three months after implant placement, a CAD/CAM screw-retained titanium-resin implant bridge was inserted in the maxilla.

Clinical follow-up

Clinical and radiological follow-up was performed at 6, 12 and 24 months. The prosthesis was removed at each follow-up to evaluate individual implant mobility, presence of pain, osteonecrosis and/or suppuration. After 24 months all implants were clinically and radiographically successful osseointegrated, no osteonecrosis and no suppuration was observed (Figure 6). The implant stability quotient (ISQ) values ranged from 50 to 62, with an average of 56.6 ± 4.5 after surgery and an ISQ values ranged from 50 to 59, with an average of 54.8 ± 3.3 at 24 months.

DISCUSSION

The present clinical case report describes a guided surgery technique and shows that the technique can be used in osteoporotic patients, as long as a strict clinical protocol is followed and the clinician is properly trained.

The use of dental implants in patients suffering from skeletal osteoporosis was long considered contra-indicated since type IV bone or “soft bone” was considered to be more prone to early implant failure.⁹ However, more recent studies have found no contra-indications for the use of dental implants in patients with osteoporosis even though a correlation was found between skeletal and jaw bone density.¹⁰⁻¹²

Van Steenberghe et al. reported an implant cumulative survival rate after 5 years of 91.5% for implants placed with guided surgery and immediately loaded with fixed prostheses. They found that implants placed in non-smokers

performed better than implants placed in smokers, both in terms of survival rate (98.9% vs. 81.2%) and mean marginal bone loss (1.2 mm vs. 2.6 mm).¹³ This indicates that extra precaution should be taken when performing guided surgery in patients with known risk factors. Further longitudinal comparative studies should be conducted to understand long-term success rate.

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A retrospective analysis of the use of 3.25 mm Neoss ProActive implants for single tooth replacements and short bridges following both immediate and conventional loading protocols

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This retrospective analysis of 110 narrow implants (Neoss ProActive 3.25 mm) in 75 patients showed a survival rate of 98.2% after an average follow up of 4.3 years (range 0.5 – 8 years).

INTRODUCTION

The use of narrow implants (< 3.5 mm) is indicated in cases with narrow tooth gaps, typically for replacement of lower incisors and upper laterals. Narrow implants are also useful in areas of thin bone as an alternative to bone regenerative procedures. The reliability of narrow implants has been demonstrated in several studies when using conventional loading protocols.¹ Narrow 3.3 mm implants have also been reported to be successful when loaded 6-10 weeks after surgery,² as well as within 48 hours after surgery.³ However, fractures due to long-term fatigue have been described for some narrow implant types.^{4,5}

The aim of this study was to retrospectively analyze the survival and fracture rates of 3.25 mm Neoss ProActive implants when used for single tooth replacements and short bridges in the anterior regions of both jaws.

MATERIALS AND METHODS

A total of 75 patients (38 female, 37 male, mean age 56.2 ± 14.5 years), who had received 110 narrow implants (Neoss

ProActive, 3.25 mm in diameter, Harrogate, UK) to support 42 single tooth replacement and 35 partial bridges in four clinics were included in the analysis (Table 1). Data was collected on average 4.3 ± 2.0 years after surgery (range 0.5 to 8 years). The implants had in general been placed following the drilling protocol as recommended by the manufacturer, i.e. using spiral drills of 2.2 and 2.85 mm in diameter and, if needed, a countersink bur. Forty-nine

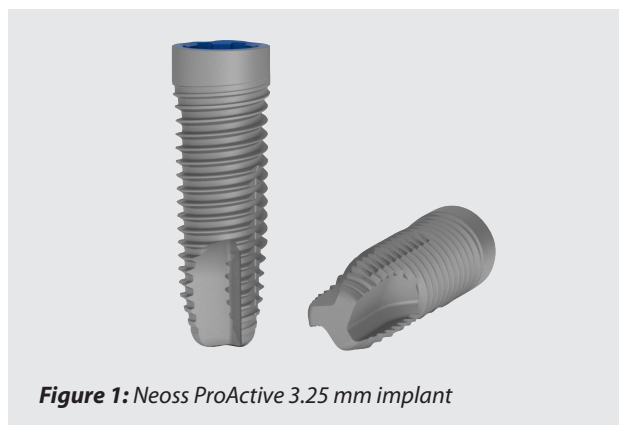


Figure 1: Neoss ProActive 3.25 mm implant

Parameter	Group	n	%
Clinic	Clinic 1	29	24.6
	Clinic 2	21	19.1
	Clinic 3	26	23.6
	Clinic 4	34	30.9
Jaw	Maxilla	38	34.5
	Mandible	72	65.5
Position	Upper lateral incisor	23	20.9
	Lower incisor	59	53.6
	Other	28	25.5
Implant length	9 mm	3	2.7
	11 mm	20	18.2
	13 mm	47	42.7
	15 mm	40	36.4
Loading protocol	Immediate	49	44.5
	One-stage delayed	14	12.7
	Two-stage delayed	47	42.7
Type of prosthesis	Single crown	42	38.2
	Partial bridge	68	61.8

Table 1: Baseline parameters

(49) implants were loaded immediately or within 3 days after surgery, and 61 implants were allowed to heal some 3 months prior to loading. For immediately/early loaded implants, an impression was taken for manufacturing of a provisional crown or short bridge or a premade construction was adapted to temporary abutments after surgery. Care was taken to avoid occlusal contacts. The provisional constructions were later replaced by permanent ones. The remaining implants received either a cover screw or a healing abutment until abutment connection and/or impression for a permanent construction (Figure 1).

Data regarding complications such as fracture and implant failure was obtained from the patient charts. No ra-

Time interval	Implants	Failed	Withdrawn / Not followed	CSR
Insert. - Load.	110	2	0	98.2%
Load. - 1 year	108	0	4	98.2%
1 - 2 years	104	0	15	98.2%
2 - 3 years	89	0	5	98.2%
3 - 4 years	84	0	6	98.2%
4 - 5 years	78	0	19	98.2%
5 - 6 years	59	0	31	98.2%
6 - 7 years	28	0	14	98.2%
7 - 8 years	14	0	9	98.2%
8 years	5	-	-	-

Table 2: Life table

diographic analyses were made in this preliminary study.

The study was conducted in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki. All patients were carefully informed about the procedure and gave their written consent to the treatment. Ethical approval is not required in Italy for retrospective quality assurance studies of routine treatments.

RESULTS

Two implants failed, which gives a survival rate of 98.2% after a mean follow-up of 4.3 years (Table 2). Both failures occurred in the mandible shortly after placement (4 and 8 weeks postoperatively). One implant was subjected to immediate loading and one received a healing abutment at surgery. Thus, the survival rates for immediately loaded and conventional protocol implants were 98.0% versus 98.4%, respectively.

The primary stability was 70.0 ± 6.7 ISQ based on measurements of 83 of the 110 implants at placement surgery.

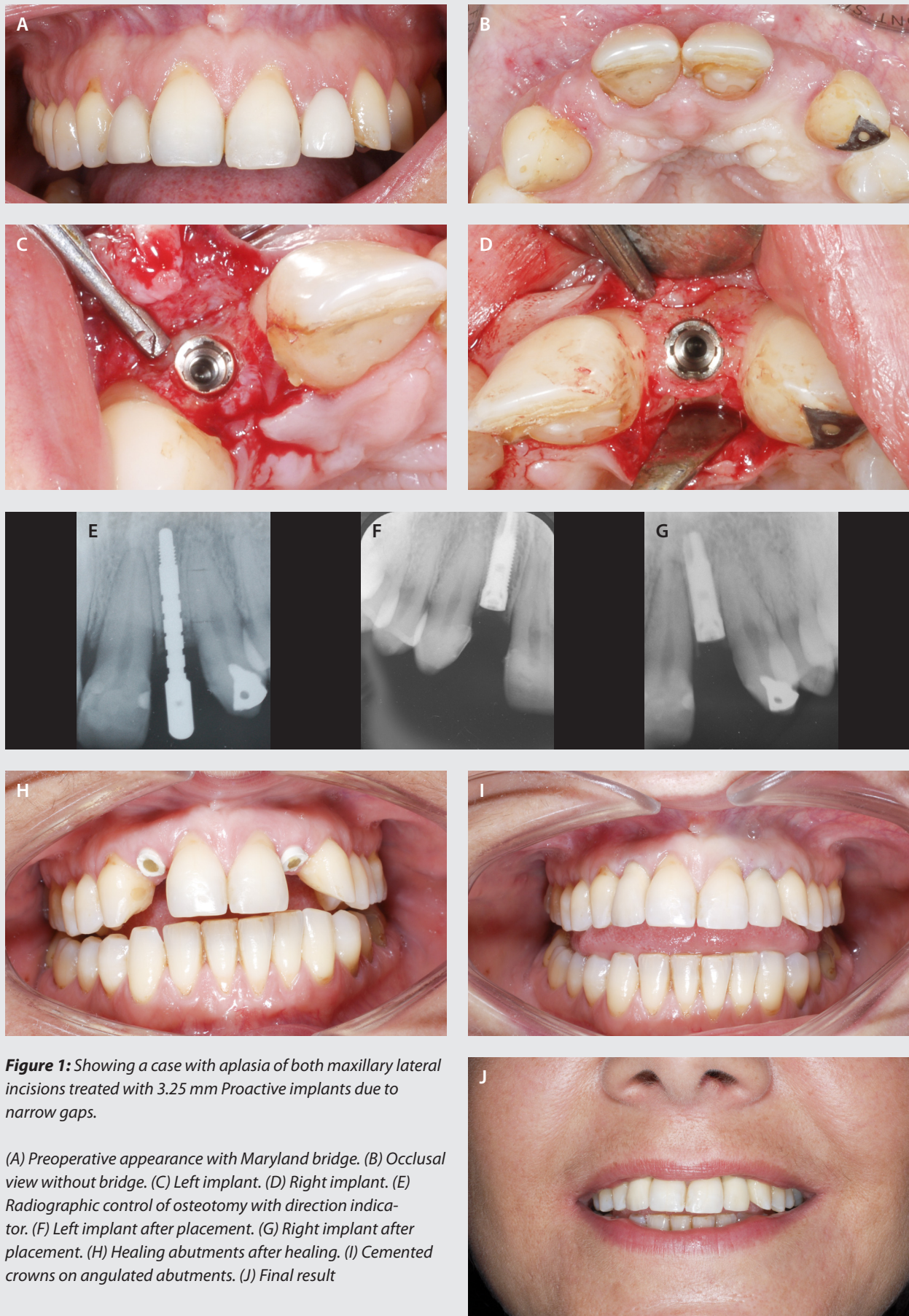
No implant fractures or other major complications were reported.

DISCUSSION

The present retrospective report showed that narrow Neoss Proactive implants can be used in clinical routine for replacement of small teeth and utilized in narrow bone sites with good results, as only two of 110 implants failed during the 0.5 to 8 years of follow-up. A systematic review of the literature showed an overall survival rate of 97.2% for 672 narrow implants with a diameter of 3.0 to 3.25 mm, which further supports the idea that the use of narrow implants is an effective treatment option.¹

According to the surgeons, firm primary stability was easily obtained with this implant, an observation that was confirmed by the ISQ measurements. Only one of 49 immediately loaded implants failed, which indicates that the implants integrated well in spite of the loading protocol. This is in line with Lambert and co-workers, who reported a 97.4% one-year survival rate for 39 narrow implants (3.3 mm) in 20 patients in both anterior and posterior areas with reduced thickness (< 6 mm) of the alveolar crest.³ In a multicentre study, 97 narrow implants (3 mm) were placed in 69 patients and loaded after 6-10 weeks with a permanent fixed prosthesis.² The authors reported on a survival rate of 95.5% and stable bone levels. It should be noted that the immediately loaded implants in the present study were, if possible, out of occlusion.

A limitation of the present preliminary report is that no radiographic analyses of the implants were made. Thus, any statements regarding the marginal bone conditions



cannot be done.

It is concluded that the 3.25 mm Neoss ProActive implant obtains firm primary stability and results in high survival rates also when immediate loading protocols are used.

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Simultaneous total extraction and implant placement in the maxilla for early loading of a fixed bridge within 3 days. A 1 to 6 year follow-up study

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The present paper reports on extraction of remaining maxillary teeth and simultaneous implant placement for loading of a fixed provisional bridge within 3 days. A retrospective evaluation of 43 cases shows a survival rate of 96.5% after one to six years of follow-up. All but one patient (97.7%) could be restored as planned.

INTRODUCTION

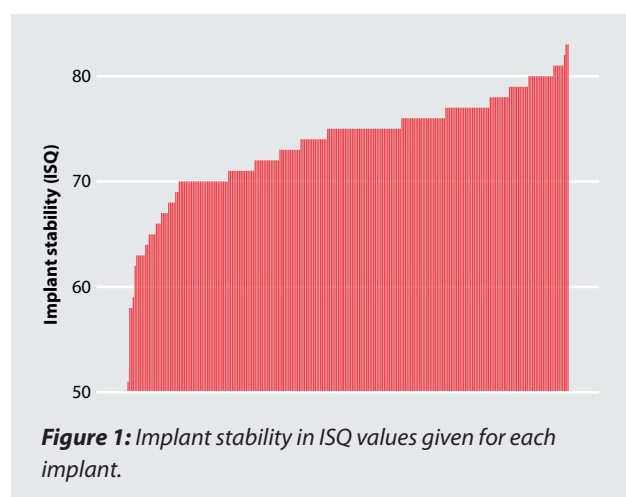
Extraction of remaining teeth and simultaneous implant therapy may be the most rational solution for many patients with a remaining diseased dentition. The benefits are evident, as the patient will receive a fixed bridge through one surgical procedure without the need for removable dentures and healing periods. Although immediate/early loading is a straightforward approach in the mandible according to the literature, the same treatment in the maxilla is less well documented, particularly when implants are placed in fresh extraction sites.¹ Due to the more frequent presence of low bone density compared to the mandible and limited bone volumes under the nose and maxillary sinuses, increased implant failure rates may be expected. However, implant stability measurements and avoiding loading of implants with low primary stability may reduce the risk for failures.²

The aims of the investigation were to study (i) implant stability, (ii) implant survival and (ii) marginal bone levels in consecutive patients treated with total extraction, simultaneous implant placement and early loading with a provisional fixed bridge in the maxilla during 1 to 6 years.

MATERIALS AND METHODS

A total of 43 patients (25 female, 18 male) had their remaining maxillary teeth (2 to 11 per patient) extracted and a total of 258 implants placed during the same surgical procedure. One-hundred eighty-two (182) implants were Neoss ProActive Straight and 76 were Neoss ProActive Tapered (Neoss Ltd, Harrogate, UK). Implant diameters ranged from 3.5 to 4.5 mm, and implant lengths from 9 to 15 mm. All patients received between 5 and 7 implants.

All implants were analysed with Resonance Frequency Analysis (RFA) in Implant Stability Quotient (ISQ) units (Osstell AB, Göteborg, Sweden).² Sterile 18 mm long impression copings were attached to the implants whereafter the soft tissues were adjusted and sutured. An impression was taken using an individual tray. Healing abutments were connected and a bite registration was taken using an individual tray, which was supported by the palate and the opposing dentition/denture as determined in pre-surgical casts mounted in an articulator. After 1 to 3 days, a screw-retained acrylic provisional bridge made on temporary titanium abutments and a metal framework was connected. Three to nine months after surgery, the implants



were re-evaluated with RFA and a permanent bridge was manufactured and delivered. The patients were clinically and radiographically evaluated at annual check-ups.

The study followed the World Medical Association Declaration of Helsinki and the directives given by the local ethical committee at the Feltre Hospital, Feltre, Italy, which does not require ethical approval for retrospective clinical studies.

RESULTS

The average implant stability at insertion was 73.8 ± 4.7 ISQ (Figure 1). Five implants were not early loaded due to low primary stability (mean 63.5 ± 7.6 ISQ) but were included in the permanent bridge.

Follow-up parameters

The present study reports the implant and bridge survival rate after 1 to 6 years and marginal bone levels after at least 5 years of function ($n = 71$).

A total of 9 implants in 5 patients were lost giving a survival rate of 96.5% after 1 to 6 years of loading. All failures were discovered when the provisional bridge was unscrewed to be replaced with a permanent one. The failed

Bone level after 5 years

Mean	1.2 mm
Standard deviation	0.8 mm
Range	0 - 4.4 mm
Number of implants	71

Frequency analysis	n	%
0 - 1 mm	33	46.5
1 - 2 mm	30	42.3
2 - 3 mm	4	5.6
> 3 mm	4	5.6

Table 1: Bone levels

implants had a similar primary stability (mean 73.2 ± 7.6 ISQ) as the successful ones. All but one patient could be restored as planned (97.7%). One patient who lost 5 of 6 implants had new implants inserted and eventually got a permanent fixed bridge.

The marginal bone level was situated on average 1.2 ± 0.8 mm from the implant shoulder after 5 years (range 0 to 4.4 mm). 84.5% of all implants had the bone level at the 1.9 mm high implant collar, indicating no threads exposed to the soft tissue.

DISCUSSION

The present study showed that full-arch clearance of remaining teeth in the maxilla and simultaneous placement of 5 to 7 Neoss ProActive implants for early loading of a full-arch bridge is feasible in patients with a severely diseased partial dentition. The overall implant survival rate of 96.5% is in line with the results from studies using other types of surface-modified implants.³⁻⁵ Our experience with this treatment modality shows that early involvement of the laboratory technicians and thorough treatment planning is of utmost importance. In particular, the use of individual trays for impression and bite-registration have

Patient	Gender	Position	Diameter	Length	Bone quantity	Bone quality	ISQ
1	Male	15	4.5	11	C	3	67
2	Female	15	4.0	15	B	2	62
		13	4.0	15	B	2	79
		11	4.0	13	B	2	75
		22	4.0	13	B	2	79
		25	4.0	13	B	2	78
3	Male	23	4.0	13	B	2	80
4	Female	21	4.0	13	B	3	74
5	Female	11	4.0	15	B	2	65

Table 2: Specification of failed implants



Figure 2: Patient subjected to total extraction and placement of 7 implants. (A-B) Initial situation. (C-D) After healing for 3 days, a provisional bridge is connected. (E-F) Permanent bridge. (G) Radiographs after 5 years.

facilitated treatment and resulted in optimal fit of the provisional bridges. It is also likely that both the geometry and surface properties of the Proactive implants contributed to the good results.

The primary stability of ProActive Straight and Tapered implants was evaluated in an in vitro study, where both designs showed firm stability but the tapered design showed even higher stability in soft bone densities.⁶ In the present study ISQ measurements were used to identify implants with low primary stability, which were not included in the provisional bridge. The moderately rough and hydrophilic ProActive surface is produced by blasting and etching which results in faster osseointegration compared to less rough implant surfaces.^{7,8} The mean marginal bone level was still on the 1.9 mm high implant collar after 5 years (1.2 mm from the reference point), which is in line with a previous study on Neoss implants.⁹

It is concluded that extraction of all remaining teeth and simultaneous placement of ProActive implants for early loading of a provisional bridge in the maxilla, is a reliable treatment modality.

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The evolution of the Neoss implant system: A retrospective follow-up of three patient cohorts treated with three types of Neoss implants

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This article reports on three patient cohorts with three types of Neoss implants. The retrospective analysis shows excellent long-term results with the Neoss implant system. The results also indicate that the introduction of the ProActive implant surface led to improved clinical outcomes in difficult cases.

INTRODUCTION

The effect of dental implant design changes on the clinical outcome is usually difficult to study in a structured way. When comparing study data from different studies, several factors change together with the change of implant design.

Here we have a clinical material where the same surgical protocol has been used by the same surgeon at the same clinic but with three generations of Neoss implants. That gives us a unique opportunity to study the effect of implant design changes in a more controlled manner.

For each new generation of Neoss implants - i.e. Bimodal Straight, ProActive Straight and ProActive Tapered - the clinical outcome of the first 50 consecutive patients treated in one private office has been retrospectively analyzed. Data on the Bimodal and the ProActive Straight patient groups have been published earlier.^{1,2}

MATERIALS AND METHODS

Patients

This retrospective study analyzes three patient cohorts consisting of the first 50 consecutive patients treated with three types of Neoss dental implants (Neoss Ltd, Harrogate, UK):

- Bimodal Straight implants
- ProActive Straight implants
- ProActive Tapered implants

The Bimodal implant had a straight implant body with a blasted surface. The ProActive Straight implant has exactly the same implant geometries as the Bimodal implant, but with the blasted and etched hydrophilic ProActive implant surface. The ProActive Tapered implant has the same ProActive surface, the same prosthetic connection and cutting features as the ProActive Straight implants but with a tapered implant body.

The patients were examined clinically and radiographically before treatment. They were thoroughly informed of the surgical and follow-up procedures and gave their written consent before treatment. All treatment steps were part of the routine procedures at the clinic, and no extra measures were taken for the cause of the study. The study was conducted in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki.

Surgical protocol

Patients were given antibiotics (Dalacin, 300 mg, Pfizer AG, Zurich, Switzerland) prior to the procedure, and the implant surgery was performed under local anesthesia (Ultracain D-S Forte, Sanofi-Aventis, Geneva, Switzerland).

In cases of localized horizontal and vertical defects, a guided bone regeneration (GBR) procedure using BioOss



and a resorbable BioGide membrane (Geistlich, Switzerland) was performed simultaneously with implant placement. Larger defects were treated using a staged GBR procedure. First, either an autologous bone block and a resorbable membrane (BioGide) or a bone substitute material (BioOss) and a non-resorbable ePTFE membrane (Gore-Tex Regenerative Membrane, Gore Medical, Flagstaff, AZ, USA) were used. Implants were placed after a healing period of 6 months. ePTFE membranes were removed in the same operation. In some cases, sinus floor augmentations were made simultaneous with implant placement either by the use of a series of osteotomes or by using a lateral window technique.

Flapped surgery was used. Implant sites were prepared and implants were placed in accordance with the manufacturer's guidelines.

Implant placement depth varied between the different treatment groups: In the Bimodal treatment cohort 59% of the implants were placed with the implant platform at bone level and 41% were placed supracrestal with half of the collar above bone level. In the two ProActive cohorts, all implants were placed with the implant-abutment connection at bone level.

Healing protocol

Three different healing protocols were utilized: Two-stage

healing, one-stage healing with delayed loading and immediate loading.

Prosthetics

Implants were restored with single crowns, partial bridges, fixed full bridges, or overdentures (Figure 1). All restorations were fabricated using conventional prosthetic techniques on NeoLink abutments (Neoss Ltd). Frameworks were made of titanium or gold, and both porcelain and acrylic were used as veneering materials.

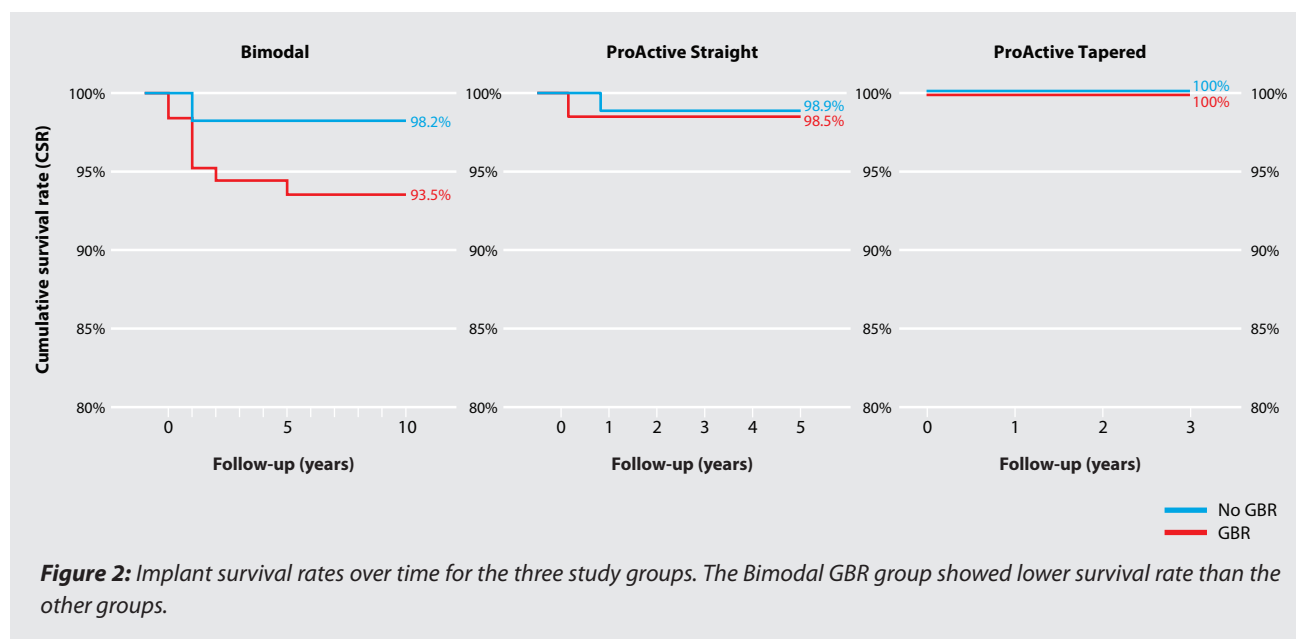
Follow-up

The patients were scheduled for annual check-ups with clinical and radiographic examination. Follow-up data was collected from the 1-, 3-, 5-, and 10-year visits.

Survival analysis was performed, and marginal bone levels were measured from periapical radiographs. Mesial and distal bone levels were measured and an average was calculated. Baseline measurements were taken at time of implant placement for the ProActive groups and at time of prosthesis delivery for the Bimodal group.

RESULTS

Baseline data, treatment schedule and follow-up status for each treatment group is presented in Figure 1.



In the Bimodal group, all followed patients have attended the 10 year check-up. In the ProActive Straight group, the patients have completed the 5 year follow-up, and in the ProActive Tapered group, the 3 year follow-up is completed (Figure 1).

Implant survival is shown in Figure 2. In the Bimodal group, the cumulative survival rate after 10 years was 93.2% for augmented sites (8 implant failures) and 98.2% for non-augmented sites (1 failure). In the ProActive Straight group, the cumulative survival rate after 5 years was 98.5% for augmented sites (1 failure) and 98.9% for non-augmented sites (1 failure). In the ProActive Tapered group, no failures occurred, resulting in cumulative survival rates after 3 years of 100% for augmented sites as well as non-augmented sites.

Marginal bone levels over time are shown in Figure 3. In the Bimodal group, the bone resorption from prosthesis delivery to 10 years was 0.4 ± 1.2 mm. In the ProActive Straight group, the bone resorption from implant placement to 5 years was 0.7 ± 0.6 mm. In the ProActive Tapered group, the bone resorption from implant placement to 3 years was 0.5 ± 0.6 mm.

All groups showed stable bone levels after the first year. None of the patients in any of the study groups showed any signs of peri-implantitis.

DISCUSSION

The three patient cohorts were treated according to the same clinical protocol. Hence, the groups were similar in gender distribution and percentage of sites requiring bone grafting. However, as clearly seen in Figure 1, the number of implants decreased for each new group. This most like-

ly reflects a shift in the general implant population over time where the percentage of full arch restorations has decreased and the percentage of single crown restoration has increased over the last 10-15 years.

The results indicate excellent long-term clinical results with the Neoss implant system. The bone levels are maintained on a stable level after one year in all groups with an average long-term bone level change in the Bimodal group between 5 and 10 years is less than 0.1 mm.

The Bimodal implant showed lower survival rate in augmented sites (93.2% vs. 98.2%). No difference in im-

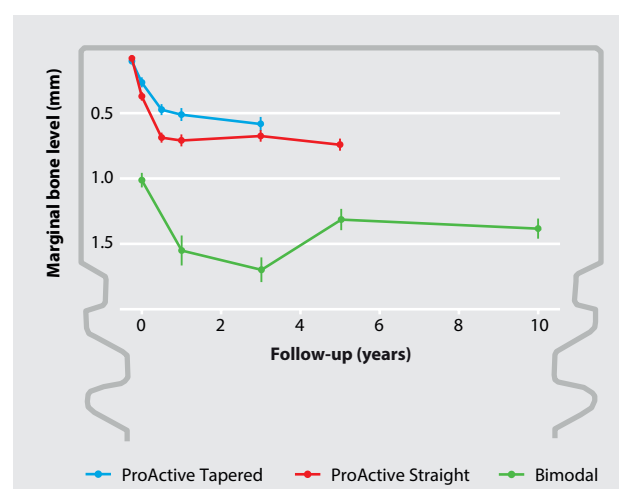


Figure 3: Marginal bone levels. All groups showed bone resorption less than 0.7 mm to the longest follow-up time-point. The bone levels in the Bimodal group is lower than the other groups, partly due to differences in placement depth.

A Neoss 4.0 mm straight implant is outlined to show the bone levels in reference to the implant collar.

plant survival between augmented and non-augmented sites were seen for the ProActive implants. This indicates that implants with the ProActive surface experience less complications than implants with the Bimodal surface. This finding is in line with earlier studies showing that ProActive implants performed better than Bimodal implants when placed directly after total extraction of remaining teeth and loaded with a fixed bridge within 3 days.³

No case of peri-implantitis was recorded in the studied patient population during the 3-10 years of follow-up. This is an interesting and encouraging finding. However, additional studies and larger patient populations are needed to establish whether this is due to the studied patient population, the surgical and prosthetic protocol, the meticulous follow-up schedule or the implant properties.

In conclusion, the studies show excellent long-term results with the Neoss implant system. The results also indicate that the introduction of the ProActive implant surface led to improved clinical outcomes in difficult cases.

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A novel biological approach to minimize the invasiveness of sinus lift therapy

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This article presents the biological rationale for a novel one-visit sinus lift procedure using a 6.5 mm wide implant specifically designed for sinus elevation and achieving primary stability with minimal bone anchorage.

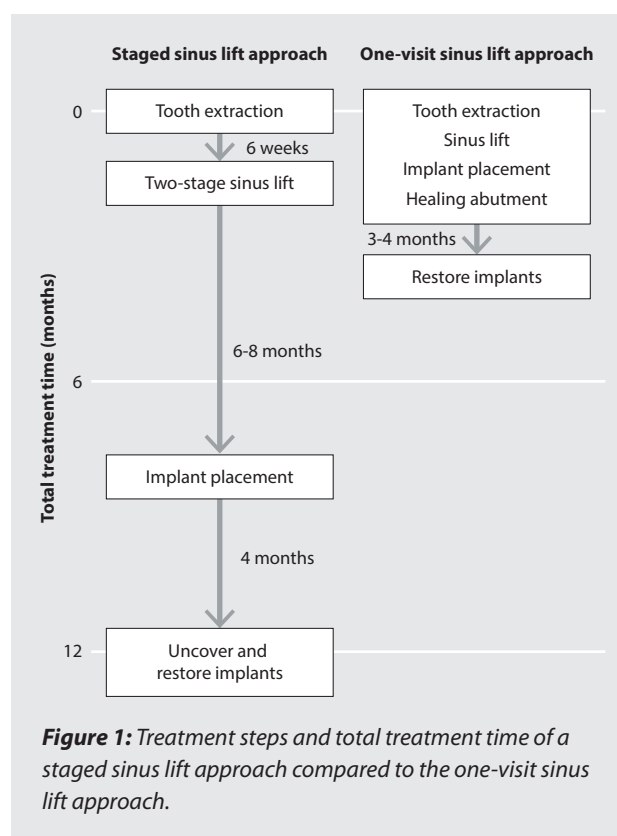
INTRODUCTION

Sinus lift is a surgical procedure that aims at increasing the amount of bone in the upper jaw to better support dental implants. The sinus is entered either through a lateral window or through the implant osteotomy and the Schneiderian membrane, that lines the maxillary sinus, is lifted to create a space that is filled with bone grafting material to form new bone.

Twenty years ago, a sinus lift was anything but non-invasive: Large lateral windows (typically 14 x 8 mm) were opened for access to the sinus. Regular platform implants Ø4 x 13 mm or Ø4 x 15 mm were used, and therefore sinus lifts of 15 mm or more were needed to accommodate the long implants. A wide range of grafting materials were used, ranging from alloplasts to xenografts and not always with the proper regeneration properties.

This invasive protocol mandated a staged approach that required long treatment times, often more than a year (Figure 1).

Over the years, technical advances have led to less invasive surgery. The advent of piezo surgery and sonic instruments have made the lateral window approach more predictable and resulted in fewer perforations of the Schneiderian membrane.^{1,2} More recently, specialized drills for the preparation of small lateral windows (5-6 mm in diameter) and drills with blunt tips for secure crestal approach procedures, as well as computer controlled pump systems to inflate the sinus with water pressure, have minimized the invasiveness of the procedure even more.



The advances in technology has made it possible to rethink the sinus lift procedure and combine good therapies and biological knowledge into a procedure with reduced treatment time and improved patient comfort without jeopardizing the clinical outcome.

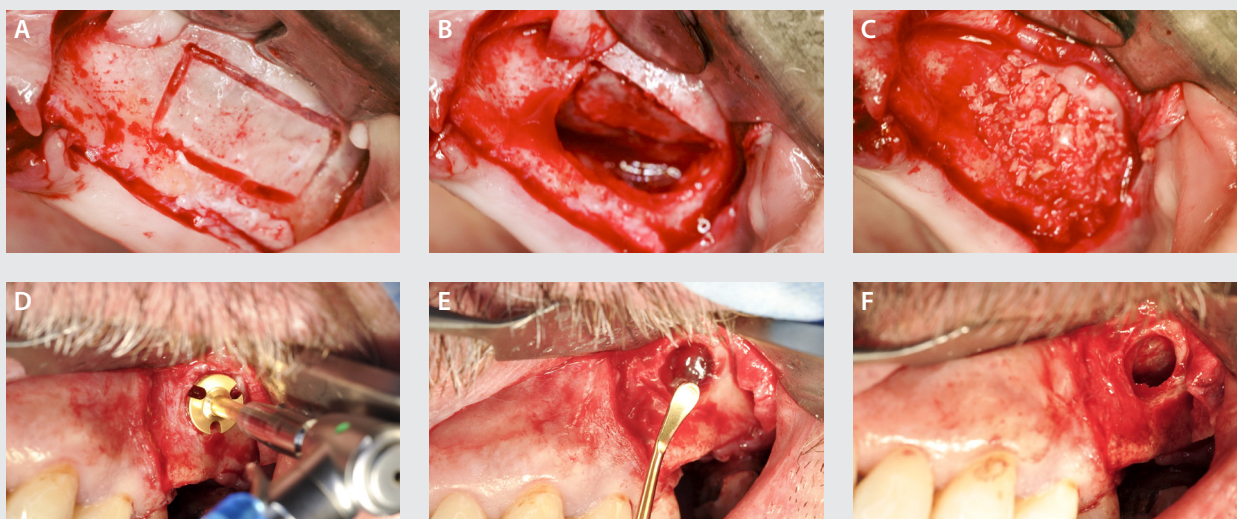


Figure 2: Traditional rectangular (8 x 15 mm) lateral window (A-C) and a less invasive drilled (Ø5.5 mm) lateral window (D-F).

Four main parameters can be altered to improve the healing rate:

- Window size
- Bone graft material
- GBR membrane
- Implant design

By optimizing these four parameters it is possible to safely go from the one year treatment using the staged approach to a procedure where tooth extraction, sinus lift, implant placement and placement of the healing abutment are done in one single visit, and where the healing time is reduced to 3-4 months (Figure 1).

Let us take a closer look at these four parameters:

WINDOW SIZE

The lateral window should be kept as small as possible. Minimizing the size of the lateral window has many benefits: The grafted site gets more stability from the surrounding walls; there is more bone left in place from where the bone formation can start; and the window itself heals faster.

Using a specialized drill kit (Sinus Lateral Approach Kit, Neobiotech, South Korea) a small window (Ø5-6 mm) can be made. Using this technique, the window area size is more than 5 times smaller than with the traditional approach (Figure 2).

If there is enough residual bone height, a crestal approach can be utilized. This makes the procedure even less invasive since there is no need for a lateral window.

BONE GRAFT MATERIAL

The bone grafting material should work hand in hand with the implant surface and the host bone during the healing process. In addition, it should be dimensionally stable and regenerated to vital bone within 3-4 months.

A cancellous particulate allograft with a particle size of 1-2 mm consisting of bone minerals and type 1 collagen (Puros Allograft Particulate, Zimmer Biomet, Palm Beach Gardens, FL, USA) has these desired properties: It maintains volume,³ and shows low levels (< 8%) of residual particles after 5-6 months in sinus lift procedures.^{4,5}

GBR MEMBRANE

It has been shown that covering the lateral window with a membrane increases the treatment success⁶ and vital bone formation⁷ compared to uncovered windows. Therefore, it is advisable to always cover the lateral window.

A resorbable membrane should be used to cover the Schneiderian membrane if the sinus is accidentally perforated or if the Schneiderian membrane is very thin (<0.3 mm).

IMPLANT DESIGN

Bone healing in the sinus has a rate of approximately 1 mm per month from the sinus walls to the implant. A distance of 6 mm from bone to implant therefore takes around 6 months to heal, whereas a 3 mm augmentation heals in approximately 3 months. By utilizing a wider implant it is possible to “bring the implant closer to the bone” and achieve faster bone healing.

In 2012, a collaboration with Neoss started to design a wider implant for the sinus.

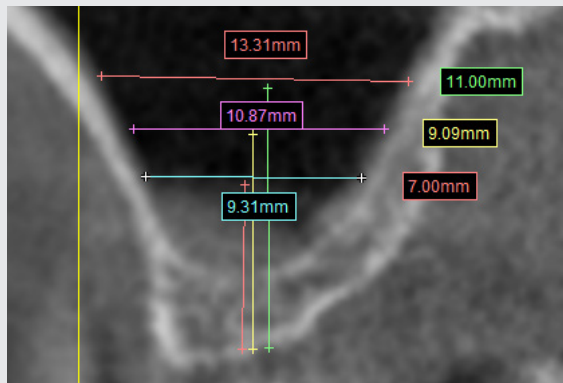


Figure 3: CBCT scan analysis of sinus dimensions. Sinus width was measured 7, 9 and 11 mm above the bone crest.

Implant diameter

Since 1996, computed tomography (CT) has been a routine tool in sinus augmentation treatment in our clinic. A sample of 100 sinus CT scans were examined to establish the average dimensions of the sinus. The width of the sinus was measured at different heights (7, 9 and 11 mm) from the crestal plane (Figure 3).

In the region of the first and second molar there is an average of 15 mm width at a height of 11 mm, and an average of 13 mm width at a height of 9 mm (Table 1). To achieve a distance between implant and sinus wall of about 3-4 mm, an implant diameter of 6.5 mm is a good size.

Sinus width	Region		
	Second premolar	First molar	Second molar
Height	11 mm	15.6 ± 1.4 mm	15.1 ± 1.8 mm
	9 mm	13.8 ± 1.3 mm	13.1 ± 1.3 mm
	7 mm	10.7 ± 1.4 mm	10.0 ± 1.2 mm

Table 1: Average sinus dimensions (n=100).

Implant length

The stability of an implant is correlated to the bone-to-implant contact (BIC), and the BIC is directly proportional to the implant surface area. As seen in Table 2, the implant surface area of a regular 4.0 x 15 mm is 253 mm². When

Implant surface area (mm ²)	Implant diameter	Implant length				
		7 mm	9 mm	11 mm	13 mm	15 mm
Implant diameter	4.0 mm	108	145	183	217	253
	5.5 mm	167	217	267	317	-
	6.5 mm	197	256	317	-	-

Table 2: Implant surface are (mm²) for Neoss implants

using a wide 6.5 mm diameter implant the same surface area (256mm²) is achieved with a 9 mm implant. Hence, by using a wider implant less bone height is needed, which in turn means that there is no need to perform a big sinus lift to get a better bone-to-implant contact.

Design features

High primary stability is essential when aiming to minimize the healing time. The Ø6.5 mm Neoss implant has the ability to achieve high stability in very little bone, through its unique collar design. The collar is conical, the threads are slightly more aggressive and extend up on the collar closer to the implant platform. This combination creates a threaded wedge that is engaging even when the available bone height is very limited.

The implant also has a rounded apex to minimize sharp edges that could tear the Schneiderian membrane during insertion and healing.

CONCLUSIONS

By combining the technical and scientific advances that has been made over the last decades, a sinus lift procedure has been developed where tooth extraction, sinus lift, implant placement and abutment connection are done in one visit. By utilizing a wide (Ø6.5mm) implant specifically designed to achieve high stability in very limited bone, the healing time is minimized and the definitive restoration can be placed within 3-4 months. The concept is summarized in Figure 4.

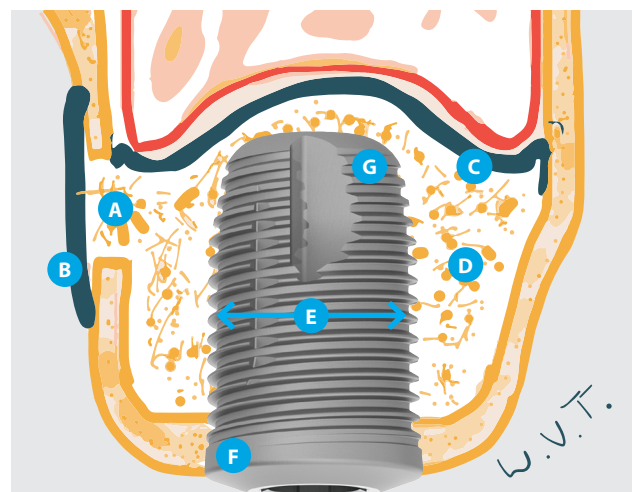
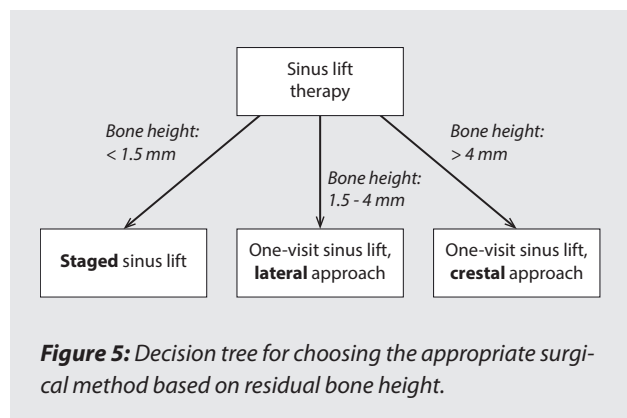


Figure 4: Factors influencing healing time. (A) Small lateral window for faster healing. (B) Cover window with membrane. (C) If the Schneiderian membrane is perforated or very thin, cover with GBR membrane. (D) Allograft material. (E) Wide implant body minimizes graft width. (F) Highly engaging collar design. (G) Rounded apex.

Deciding what sinus lift approach to use

When is it safe to go for a crestal approach, when should a lateral window be opened, and in which cases should a staged approach be chosen? The height of the residual bone is the deciding factor. A decision flowchart is shown in Figure 5.



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The Sinus implant. A case series on Neoss 6.5 mm ProActive implant for sinus elevation

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This article presents five cases where a one-visit approach is used for sinus elevation surgery. The article also summarizes the clinical outcome of the 99 patients treated with the Neoss ProActive 6.5 mm implants. One implant of the 161 placed has failed, resulting in a survival rate of 99.4%.

INTRODUCTION

Sinus elevation procedures that aim at increasing the available bone in the upper jaw for implant anchorage have historically been very invasive and time consuming.

A novel method where tooth extraction, sinus lift, placement of wide implants (ProActive 6.5 mm implants, Neoss, Harrogate, UK) and placement of the healing abutment are done in one single visit, has been described. This method is less invasive and the combined healing time can be reduced to 3-4 months.¹

The aim of the present article is to present clinical cases where this novel surgical procedure is used, and to report

preliminary results on the use of Neoss ProActive 6.5 mm implants, predominantly in sinus elevation procedures.

CASE REPORTS

Five clinical cases are presented where the one-visit sinus lift procedure is utilized. Three of the cases were done using the lateral approach and the remaining two cases using the crestal approach.

Case 1: One-visit lateral sinus lift. 52 years old female with severe periodontitis. This case was treated in June 2013 and it was the first patient ever to be treated with a Neoss ProActive 6.5 mm implant.



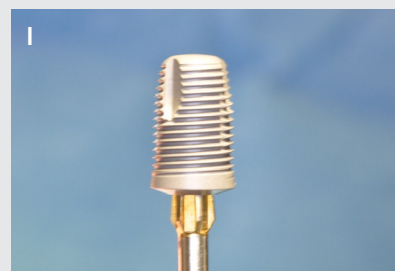
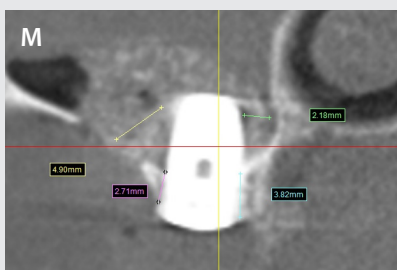
A: Initial situation. Severe periodontitis. Extraction of the first upper molar required.

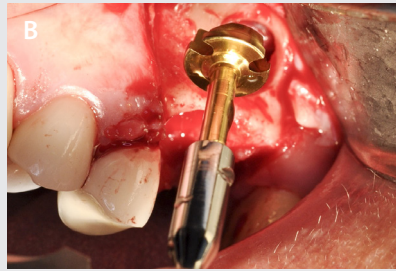
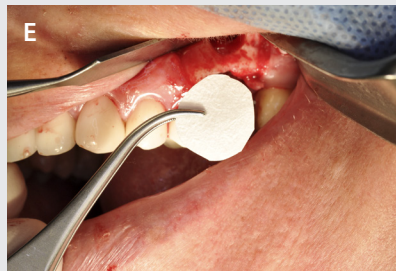
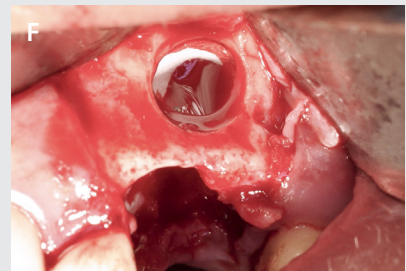
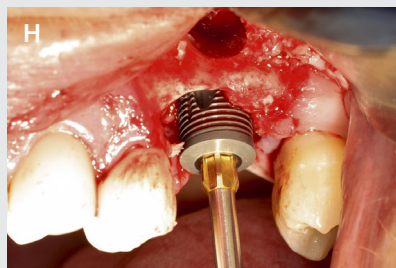
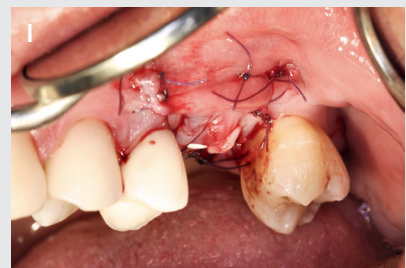
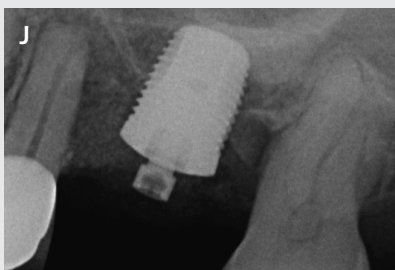
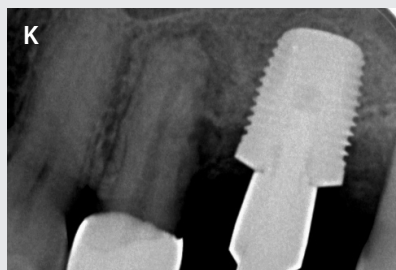


B: Initial radiograph shows periodontal problems and limited residual bone height below the sinus.

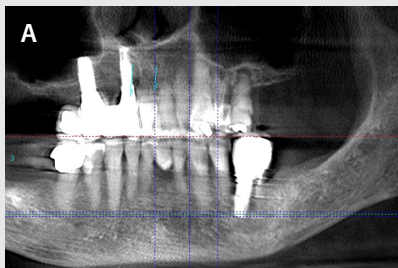


C: First upper molar extracted.

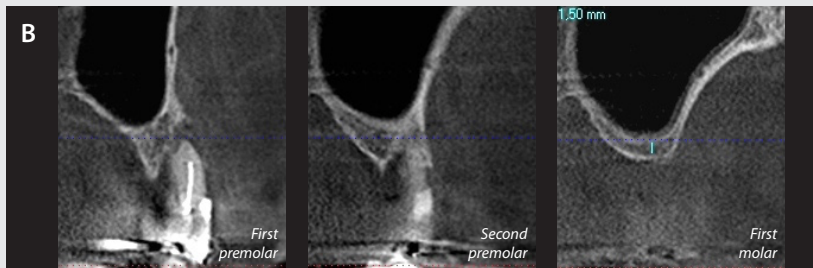
Case 1: continued**D:** CBCT after extraction.**E:** A small lateral window is drilled using a specialized drill kit (Sinus Lateral Approach Kit, Neobiotech)**F:** A resorbable collagen membrane (Bio-mend, Zimmer Biomet) is fitted to protect the very thin Schneiderian membrane.**G:** Collagen membrane in place**H:** The augmentation is filled with a hydrated particulate allograft (Puros, Zimmer Biomet).**I:** The first Neoss ProActive 6.5 x 11 mm implant.**J:** Implant insertion.**K:** Good primary stability is achieved (ISQ 80/75). Compaction of graft material is achieved.**L:** The lateral window is covered with a resorbable collagen membrane (CopiOs, Zimmer Biomet)**M:** CBCT after implant placement. After 4 months of healing, ISQ increased to 85/85.**N-O:** Clinical situation 2 years post-loading.

Case 2: One-visit lateral sinus lift. 50 years old female with severe periodontal problems in the first molar area.**A:** Residual bone height 2 mm only.**B:** A lateral window (Ø 5.5 mm) is drilled.**C:** The Schneiderian membrane has been lifted, and the implant osteotomy is prepared.**D:** The last drill in the drill sequence is the 6.5 mm Counterbore.**E:** Fitting of collagen membrane.**F:** Collagen membrane in place covering the Schneiderian membrane.**G:** Augmentation filled with particulate allograft.**H:** Insertion of a 6.5 x 9 mm implant. An insertion torque of 40 Ncm and ISQ 66 is reached, indicating good stability.**I:** A PEEK healing abutment is connected, and the flap is closed.**J:** Radiograph at implant placement. Note the limited bone height.**K:** After 4 months, at time of loading, ISQ has increased to 77. Note the increase in bone quality around implant.**L:** Clinical situation 12 months after loading.

Case 3: One-visit lateral sinus lift. 84 years old female. Decay in the premolar area, molar teeth missing. Patient already had implants 20 years ago. Wanted fixed teeth while not undergoing too many operations.



A: CBCT image of clinical situation before treatment.



B: CBCT analysis. Residual bone height is 3mm in the first premolar area, 2.5 mm in the second premolar area, and only 1.5 mm in the first molar area.



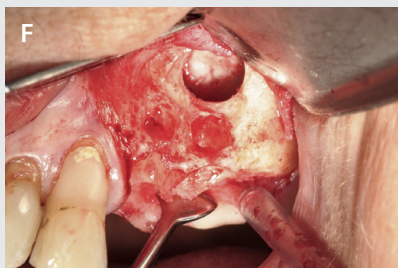
C: Initial situation.



D: First and second premolars extracted.



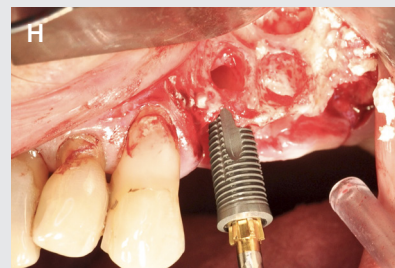
E: Lateral window opened to expose the Schneiderian membrane. Two cysts (arrows) to be removed.



F: Sinus membrane lifted and cysts removed.



G: The two implant sites are prepared. Note the extremely thin sinus floor (1.5 mm) in the molar area.



H: After filling with allograft material, a ProActive Tapered 4 x 13 mm implant is inserted in the first premolar area.



I: Insertion of a ProActive 6.5 x 11 mm implant in the first molar area.

J	First premolar	First molar
Implant dimensions	4 x 13 mm	6.5 x 11 mm
Stability (ISQ)	70	83
Insertion torque	32 Ncm	23 Ncm

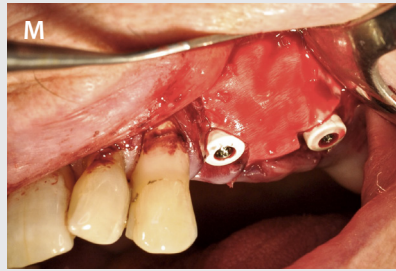
J: Implant insertion parameters.



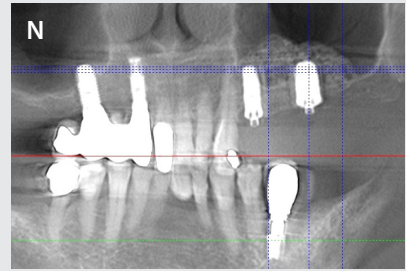
K: Seated implants.

Case 3: continued

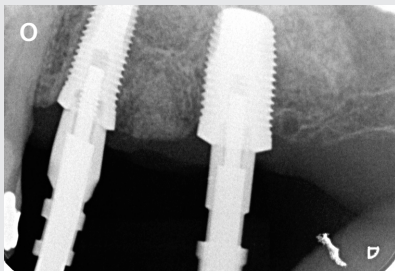
L: Healing abutments connected to the implants. Allograft material covering the perforated bone.



M: Grafting material covered with a collagen membrane (Biomend, Zimmer Biomet).



N: CBCT image directly after implant placement. Note the grafting material on top of the sinus floor.



O: After 4 months, the graft has been re-generated to bone and ISQ has increased from 70 to 77 and from 83 to 86.



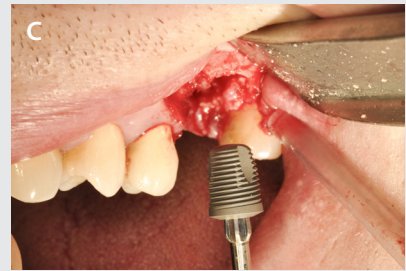
P-Q: Clinical situation 17 months after loading.

**Case 4: One-visit crestal sinus lift.** 37 years old male with root resorption on first molar.

A: Upper first molar with root resorption. Residual sinus floor height 3 mm.



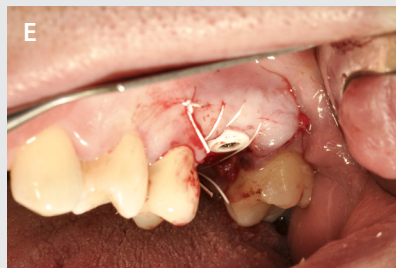
B: First molar extracted. Augmentation with crestal approach through the implant osteotomy.



C: Note the decreased invasiveness of the procedure compared to the lateral window cases.



D: Insertion of a ProActive 6.5 x 9 mm implant. Insertion torque 48 Ncm, ISQ 68/70.



E: PEEK healing abutment connected to implant for transgingival healing directly after surgery.



F: Good soft tissue conditions after 4 months healing.

Case 4: One-visit crestal sinus lift

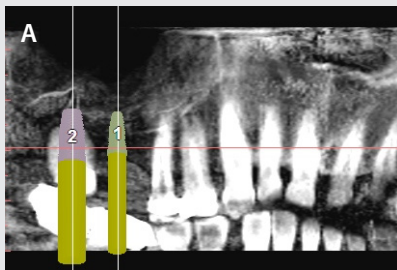
G: Implant stability (ISQ) increased from 68/77 to 76/82 after 4 months healing.



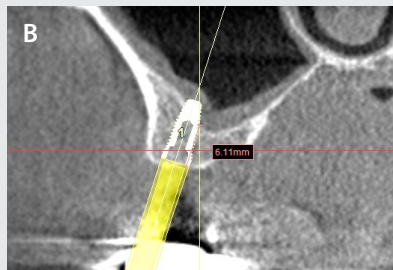
H: Radiograph after 4 months healing show new bone around the entire implant.



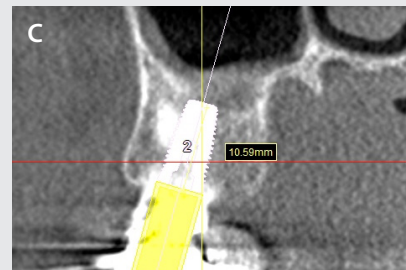
I: Definitive prosthesis in place.

Case 5: One-visit crestal sinus lift. 62 years old male. First molar missing, decay second molar area.

A: CBCT planning for two implants in the upper molar area.



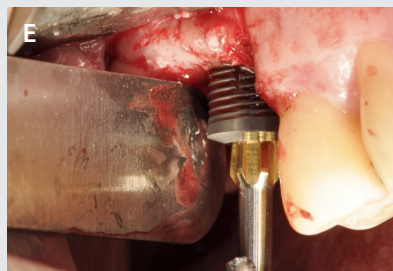
B: Residual bone height 8 mm in the upper first molar area.



C: Residual bone height 10 mm in the upper second molar area.



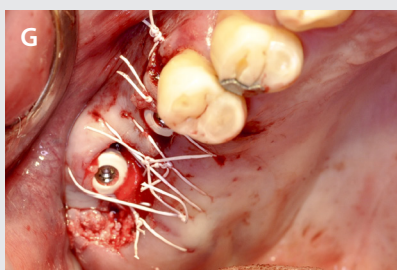
D: Extraction of upper second molar. Since bone height is sufficient, a crestal approach is used.



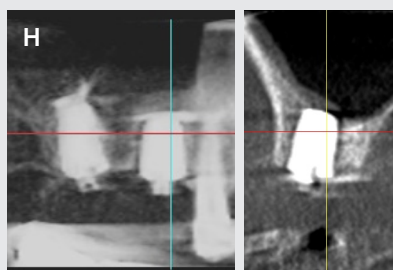
E: Insertion of a ProActive 6.5 x 9 mm implant in the first molar area.

F	First molar	Second molar
Implant dimensions	6.5 x 9 mm	6.5 x 11 mm
Stability (ISQ)	77	70
Insertion torque	42 Ncm	38 Ncm

F: Implant insertion parameters.



G: Soft tissue closure around PEEK healing abutments for transgingival healing.



H: CBCT images (two views) directly after placement. Palatal augmentation in first molar area clearly seen in second image.



I: Clinical situation 13 months after loading.

PRELIMINARY RESULTS

Ninety-nine (99) patients were treated with the 6.5 mm Neoss ProActive implant between June 2013 and June 2017. In total, 161 implants were placed.

Lengths of the placed implants are given in Table 1. The short 7 mm implant was introduced later than the 9 and 11 mm, therefore 7 mm implants are likely under-represented in this material. However, the data clearly shows that the 9 mm implant is by far the most used length and it indicates that this length is suitable in most cases.

Indications and treatment outcome are presented in Table 2. One implant failure occurred, out of 161 placed implants, resulting in a survival rate of 99.4%.

In conclusion, this case series has shown that 6.5 mm Neoss implants can be predictably placed using a one-visit sinus lift procedure. Primary implant stability can be achieved in cases with as little as 1.5 mm residual bone.

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Implant length	7 mm	9 mm	11 mm
Number of implants	7	121	33

Table 1: Number of implants placed of each length.

Indication	Number of patients	Implants placed	Failed implants
Lateral sinus lift	40	91	1
Crestal sinus lift	42	53	0
Extraction site	16	16	0
Rescue implant	1	1	0
Total	99	161	1

Table 2: Preliminary results.

NeoGen dual texture membrane. The next generation of non-resorbable e-PTFE membranes for guided bone regeneration (GBR)

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This article describes the current trends in research and development of dual texture non-resorbable membranes for guided bone regeneration (GBR).

INTRODUCTION

Guided bone regeneration (GBR) has been defined as “the principle of using barrier membranes to exclude certain cell types such as rapidly proliferating epithelium and connective tissue, thus promoting the growth of slower-growing cells capable of forming bone”. The concept has been in clinical use since the early 90s and is still an established technique that has been spread and used globally.

Different membrane materials and modifications have been used over time. According to the original concept, certain characteristics were defined for membranes utilized for GBR therapy. These characteristics included biocompatibility, cell occlusion properties, integration by the host tissues, clinical manageability, space making ability and adequate mechanical and physical properties. Non-resorbable membranes, mainly designed as expanded polytetrafluoroethylene (e-PTFE), constituted the first generation of barrier membranes.^{1,2} These types of membranes demonstrated biocompatibility and space-making capacity due to their stable material properties. In addition, e-PTFE was considered a stable device due to the fact that it provoked only a minimal immunologic reaction.³

The initial design features were focused on maintaining a barrier function of the membranes throughout the healing period. Later, an addition of a titanium reinforcement

was introduced to prevent membrane collapse and hence improve stability and space maintenance, which was considered essential for a successful regenerative outcome.

During the last two decades, we have seen a shift of focus toward resorbable membranes mostly due to their ease of use in the clinical setting. However, in the clinical situation there is still a defined need for a non-resorbable membrane in more advanced cases, corresponding to 10–15% of all GBR procedures performed.

Whilst the definition of GBR has remained intact for more than two decades, recent findings imply that biodegradable membranes might play a significant role during the wound healing process, acting as a director and coordinator of the healing.^{4,5} More specifically, the membrane, per se, seems to host different cell phenotypes during GBR. These cells within the membrane progressively express and secrete major bone-related growth factors, including the potent pro-osteogenic factor BMP-2. The results provide strong evidence that the membrane is directly promoting the healing processes in the underlying defect by activating the host cells that are recruited into and/or become adherent to the membrane. This allows for their signals to be communicated to the different cell populations in the underlying defect.

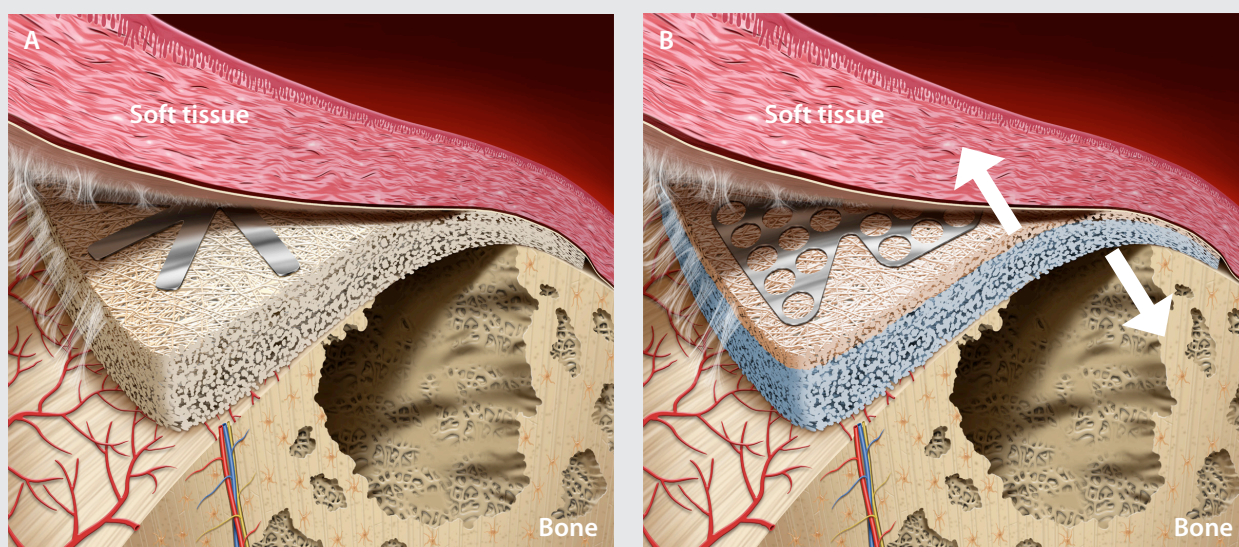


Figure 1: (A) Shows the first generation of non-resorbable membrane comprising of a uniform e-PTFE structure. (B) Shows a new dual configuration e-PTFE membrane with tailor-made surfaces facing the soft and hard tissues respectively.

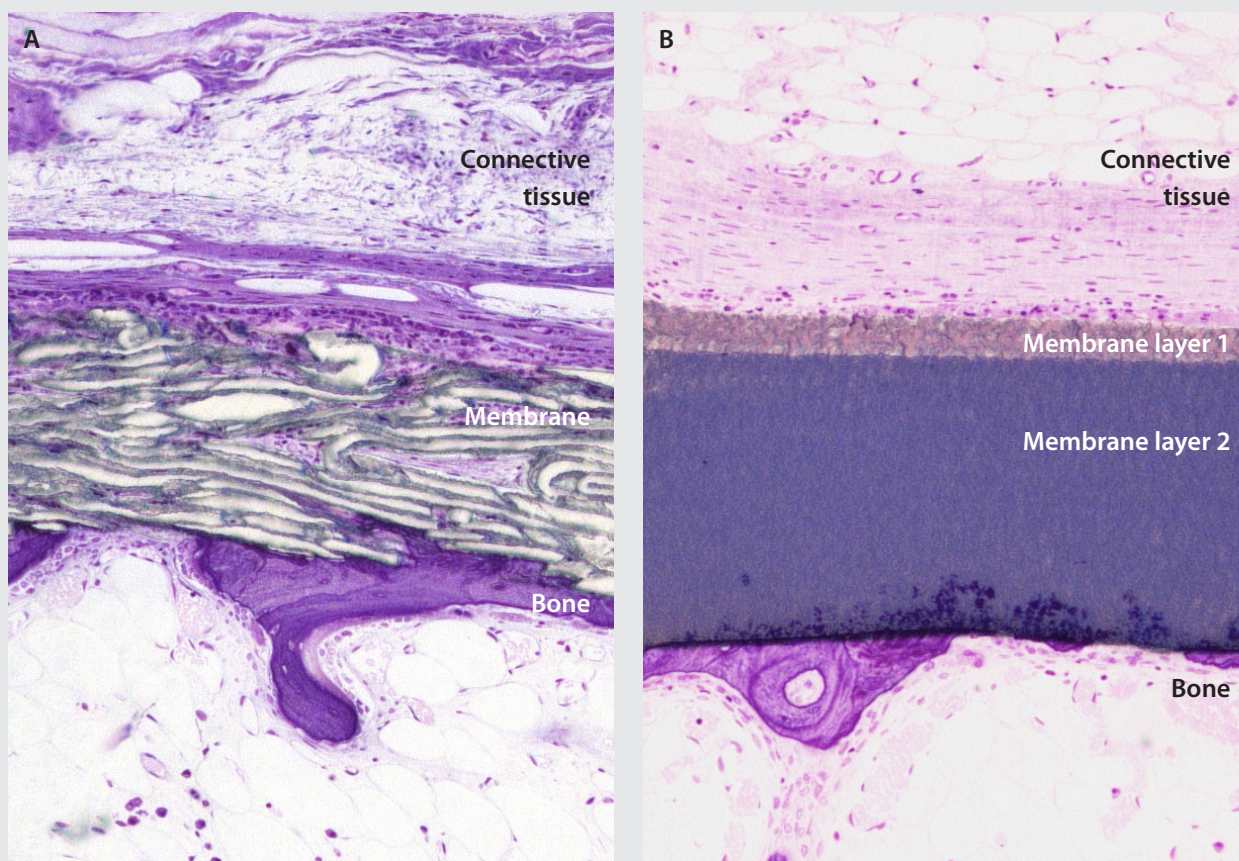


Figure 2: (A) Histological section showing biocompatibility of the first generation of uniform non-resorbable membranes (Gore-Tex). Significant ingrowth of soft tissue can be noted. (B) Histological section showing excellent biocompatibility of the dual texture NeoGen membrane. Note the interaction between the newly formed bone and the adjacent structure of the membrane as shown by mineral deposits (dark spots) into the membrane.

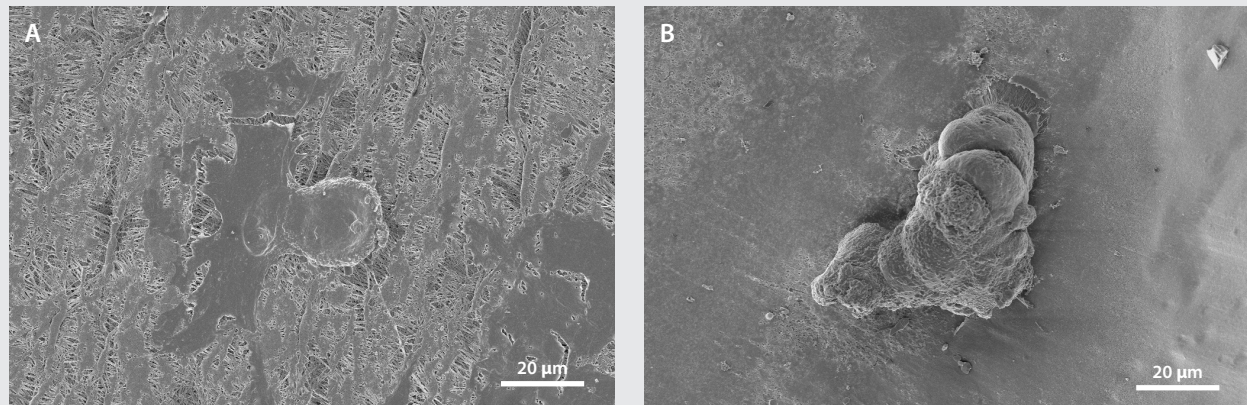


Figure 3: (A) SEM picture demonstrating a fibroblast attached to a NeoGen (e-PTFE) membrane surface. Note the healthy fibroblast morphology (spreading out on the surface). (B) SEM picture demonstrating a fibroblast attached to a d-PTFE membrane surface. The rounded cell shape indicates signs of apoptosis (non-viability).

This suggests that the traditional view of the membrane acting as a passive barrier and graft container might shift in the future into a view where the membrane plays a more active role and guides and directs the healing events during

the regenerative healing. Different tissue types, such as the surrounding connective tissue, bone tissue and blood vessels, are involved in the wound healing process during GBR healing. All of these tissue types have different specif-

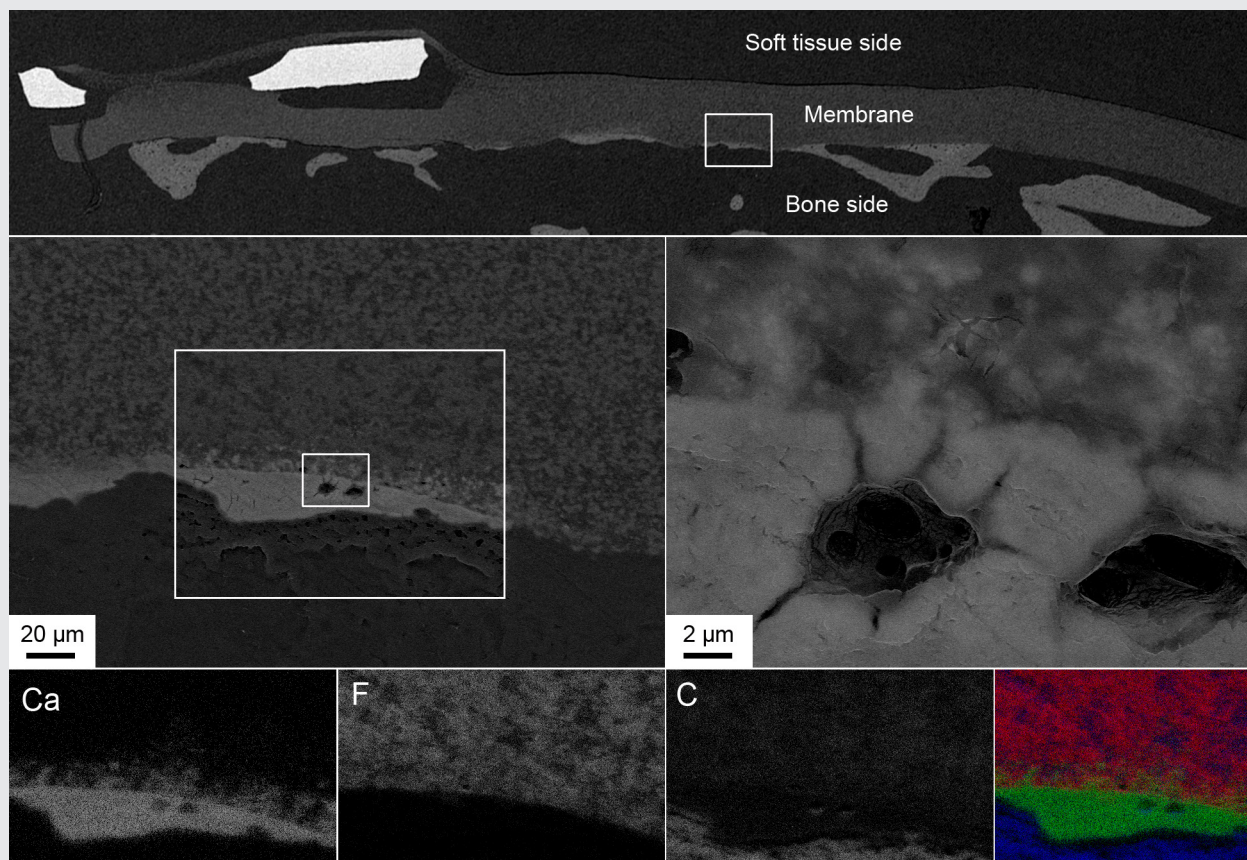


Figure 4: Backscatter SEM and elemental analysis of bone-membrane interface of a NeoGen membrane implanted in a rabbit maxilla for 4 months. Calcium (Ca) is shown in the newly deposited bone on the membrane surface, but also as mineral deposits into the adjacent membrane. The fluoride (F) content of the membrane material is clearly seen. The color composite picture on the right clearly shows the calcium deposits (green) into the membrane material (red).

ic needs during the healing process. A modern design of a membrane should be tailor-made to meet these requirements.

Despite the shift in view of the role of the membrane in GBR procedure, tailor-made membranes are still a largely unexplored field.⁶ The interactions between tissue and membrane need to be fine-tuned to balance tissue acceptance and integration on one hand and clinical manageability and retrievability on the other.

Where the first generation of non-resorbable membranes had the same principal structure facing both the soft and hard tissues (Figure 1A, 2A), the new generation of tailor-made non-resorbable membranes (NeoGen) comprise of two layers with different membrane configurations, each one adapted to meet cellular requirements from the adjacent tissue (Figure 1B, 2B). This novel material is constructed by means of multidirectional e-PTFE fibers which creates a three-dimensional structure. The material configuration has been shown to interact positively with cells in vitro compared to d-PTFE (dense) membranes (Figure 4).

Although the NeoGen membrane appears to be open in its structure, in vitro studies have demonstrated that neither cells nor bacteria are capable of penetrating the membrane material.⁷ In addition, it can have been shown that tissue fluids and exudates from the cells are deposited into the membrane material (Figure 2 and 3). This could allow a positive interaction with the adjacent tissue in a fashion similar to what has been described for resorbable membranes.^{4,5}

The field of non-resorbable membranes has been rather static for almost two decades. Now with increased biological understanding in combination with developments and increased know-how within the field of tissue engineering, we clearly see a revival for these types of membranes in the field of guided bone regeneration.

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Guided bone regeneration (GBR) using a Ti-reinforced non-resorbable PTFE membrane and simultaneous implant placement. A retrospective study

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This retrospective analysis of 84 patients treated according to a GBR protocol with simultaneous implant placement using 107 GBR membranes (NeoGen) and 139 implants (Neoss ProActive) showed an implant survival rate of 100% after an average follow up of 20.8 months after membrane removal. The average treatment time from surgery to prosthesis delivery was 7.6 months. Thirteen membrane related soft tissue complications occurred (12.1%).

INTRODUCTION

Guided bone regeneration (GBR) was introduced as a treatment concept almost 30 years ago.¹ The heart of the concept is the placement of a membrane that separates the soft tissue from the bone defect, creating a space where the slower bone-forming cells can generate new bone without the interference from soft tissue cells.

GBR can be performed in numerous ways: with resorbable or non-resorbable membranes, with or without grafting material, with or without structural reinforcement, in a staged approach or simultaneous with implant placement.²

The aim of the study was to retrospectively study the clinical outcome of a GBR procedure using a Ti-reinforced non-resorbable membrane and autogenous bone material with simultaneous implant placement.

MATERIALS AND METHODS

Study design

This retrospective study reports on the clinical outcome of the first 84 consecutive patients treated in the same clinic by one surgeon (NoH) using a surgical protocol where a guided bone regeneration (GBR) procedure using autogenous bone material and a non-resorbable PTFE membrane

(NeoGen Ti-Reinforced Membrane, Neoss, Harrogate, UK) was performed at time of implant placement.

All patients that underwent the clinical procedure were deemed appropriate through clinical and radiographic examination before treatment. The patients were informed of the procedures and gave their written consent before treatment.

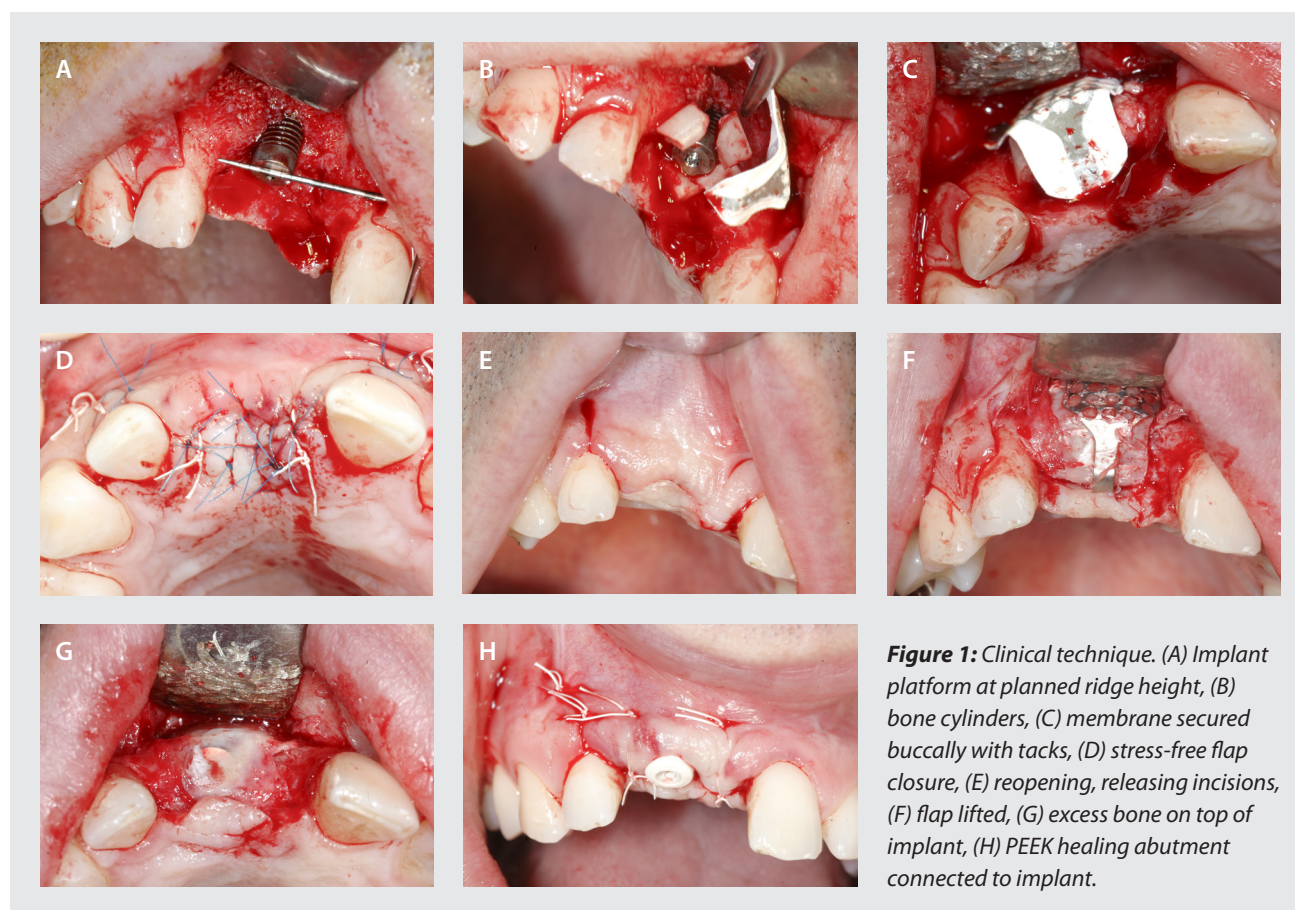
All study data was collected through a retrospective chart review. All collected data was part of the patients files, therefore no additional treatments were performed as part of this study. The retrospective data collection was conducted in accordance with the World Medical Association Declaration of Helsinki.

Treatment protocol

Antibiotic treatment was commenced the evening before surgery and lasted for 5 days. All surgeries were performed under local anesthesia

A full thickness flap with releasing incisions was opened and the implant site was prepared. Implant osteotomies were drilled according to the manufacturer's guidelines to achieve good primary stability.

Autogenous bone chips were collected during preparation of the implant osteotomies using a bone collecting



device connected to the suction system.

One or more dental implants (Neoss ProActive Straight, Neoss, UK) were placed with the implant-abutment connection at planned future bone level and a cover screw was connected (Figure 1A)

In larger defect cases, autogenous bone cylinders were used together with the autogenous bone chips to accelerate regeneration and to act as space fillers (Figure 1B). The bone cylinders (height up to 5 mm) were harvested from the oblique line of the mandible in the molar region using a 3.4 mm trephine drill. In smaller defect cases, only autogenous bone chips were used. No additional bone substitutes were used.

A Ti-reinforced membrane (NeoGen Ti-Reinforced Membrane, Neoss Ltd, Harrogate, UK) was trimmed, shaped, and fitted at the surgical site and secured buccally using membrane tacks. A stable membrane configuration was achieved using the implants as tent posts (Figure 1C).

Stress free flap closure was achieved by releasing the periosteum on the buccal side (Figure 1D).

The augmented sites were typically allowed to heal for 4 - 7 months, depending on clinical situation. After the healing period, second stage surgery was performed. A mid-crestal incision with releasing incisions was used (Fig-

ure 1E). The flap was lifted to expose the membrane (Figure 1F) and the membrane was removed. If needed, excess bone on top of the cover screw (Figure 1G) was removed to get access to the implant. PEEK healing abutments (Neoss

Parameter	Group	n	%
Defect position	Anterior maxilla	56	40.3
	Posterior maxilla	36	25.9
	Anterior mandible	11	7.9
	Posterior mandible	36	25.9
Defect type	Dehiscence	102	73.4
	Fenestration	11	7.9
	Vertical	9	6.5
	Dehiscence + Fenestration	3	2.2
	Dehiscence + Vertical	5	3.6
	Intra-alveolar	2	1.4
	Other / No information	7	5.0
Defect depth	1 - 2 mm	8	5.8
	3 - 4 mm	28	20.1
	5 - 6 mm	28	20.1
	7 - 8 mm	32	23.0
	9 - 10 mm	18	12.9
	11 - 12 mm	13	9.4
	13 - 14 mm	8	5.8
	15 - 16 mm	4	2.9
Mean ± S.D.		7.1 ± 3.4 mm	

Table 1: Defect parameters measured per implant site.

Ltd, UK) were connected to the implants for transgingival healing and the flap was closed (Figure 1H).

The definitive prostheses were delivered 0 - 18 months (average 2.8 months) after membrane removal.

Follow-up

All information on complications that led to early membrane removal, such as infection and membrane exposure, were compiled from the patient records.

The latest time-point registered in the patient's file was used for the implant follow-up. Implant follow-up time was calculated from time of membrane removal. In 56 patients (93 implant sites, 66.9%), follow-up parameters were registered according to a standardized follow-up form. For the remaining 28 patients, only implant survival data was registered.

RESULTS

Baseline data

The chart review identified 84 patients where a GBR procedure using the NeoGen membrane was performed simultaneous with implant placement. In these 84 patients, 107 membranes and 139 implants were placed. The average patient age was 53.6 ± 16.0 years (range 17 to 80). Ninety-two implants were placed in the maxilla and 47 in the

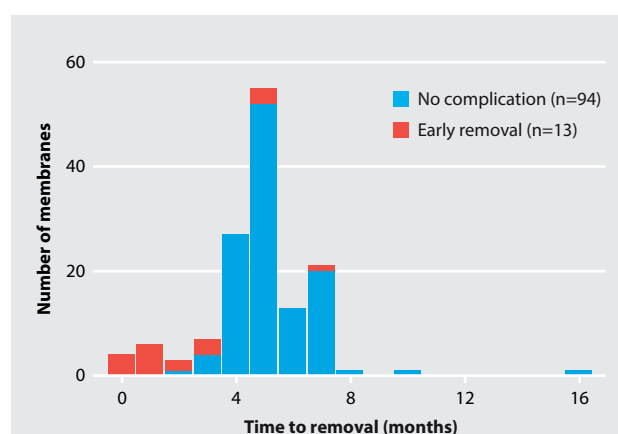


Figure 2: Membrane treatment times. Average treatment time was 4.9 ± 2.0 months.

mandible. The majority of the bony defects (73.4%) were dehiscences. The average defect depth was 7.1 ± 3.4 mm (Table 1).

Membrane treatment results

The average membrane treatment time was 4.9 ± 2.0 months (Figure 2). Thirteen (13) of the 107 membrane sites (12.1%) experienced complications that required intervention. These cases are specified in Table 2.

Patient	Age	Positions	Complication type	Timepoint	Treatment
1	74	33	Membrane exposure	2 months	Chlorhexidine rinse, membrane removal 4 days later
2	49	34	Infection	5 months	Membrane removal at time of complication
3	51	35	Membrane exposure	3 weeks	Chlorhexidine rinse, membrane removal 3 weeks later
4	72	21, 22	Membrane exposure	2 weeks	Chlorhexidine rinse, partial membrane removal 1 month later. Remaining membrane removed 14 weeks after that.
5	58	42, 44	Membrane exposure	3 weeks	Chlorhexidine rinse, membrane removal 1 month later.
6	26	22	Infection	2.5 months	Antibiotics, membrane removed at time of complication. Reaugmentation 1 months later, membrane removed after 11 months. No complications during reaugmentation.
7	63	13	Membrane exposure	3 months	Antibiotics, membrane removal 1 week later.
8	57	36, 37	Membrane exposure and infection	3.5 months	Chlorhexidine + antibiotics, membrane removal 1 week later.
9	70	14	Membrane exposure	2 months	Chlorhexidine + antibiotics, membrane removal next day.
10	50	14, 16	Membrane exposure	4.5 months	Chlorhexidine rinse, partial membrane removal at time of complication. Remaining membrane removed 1 months later.
11	22	11	Membrane exposure	7 months	Chlorhexidine + antibiotics, membrane removal next day. Reaugmentation + soft tissue graft 1.5 months later. No complications during reaugmentation.
12	67	46, 47	Membrane exposure	3 weeks	Membrane removal at time of complication
13	73	44, 46	Membrane exposure	1 week	Chlorhexidine rinse, membrane removal 3 weeks later.

Table 2: Specification of membrane complications.

Implant treatment results

Although some membranes had to be removed early, no implant failure occurred. This resulted in an implant survival rate of 100% after an average follow-up time of 20.8 ± 8.7 months (range 0 – 37 months).

All implants were restored. The average time from implant insertion and simultaneous GBR procedure to prosthesis delivery was 7.6 ± 4.8 months.

The clinical follow-up parameters (Table 3) indicate that the implant outcome is successful. No implant mobility was detected, and percussion sound indicated healthy bone around all implants. Normal levels on bleeding and probing, plaque index and gingival index as well as mean probing depths of 2.1 - 2.6 mm (max 5 mm) on all aspects of the implant indicates healthy soft tissue.

DISCUSSION

In the present study, membrane complications occurred in 12.1% of the membrane sites. This is well in line with what is reported in a recent systematic review by Lim et al. that reported an average complication rate of 17.6% for non-resorbable membranes and 18.3% for resorbable membranes.³

Membrane complications do occur, but it is not an event that automatically result in a failed treatment. On the contrary, all complications in the present study were resolved and no implant failures occurred, resulting in a 100% implant survival rate. This is in line with the results of Lim et al. They reported that the majority of studies in their systematic review achieved complete healing of the sites that had experienced complications without significant impact on the bone augmentation procedure.³

As seen in Table 2, some membranes were removed immediately when the complication occurred, whereas others were managed in situ for another month before removal. The timing of removal depended on the nature and severity of the complication.

By performing the GBR procedure simultaneous with implant placement, the healing for the GBR and implant surgeries took place at the same time, thereby shortening the treatment time with several months. This is reflected in the short average time (7.6 months) from surgery to prosthesis delivery.

Another advantage of the simultaneous approach is that the implant can act as a tent post, stabilizing the membrane during the GBR procedure. A prerequisite for this is that sufficient implant stability can be achieved.

A reason for choosing a resorbable membrane is that a second surgery to remove the membrane is not needed. However, when using the simultaneous approach the

Parameter	Group	n	%
Percussion	Bright sound	93	100
	Dull sound	0	0
Implant mobility	No	93	100
	Yes	0	0
Bleeding on probing	No	58	62.4
	Yes	35	37.6
Plaque index	0: no plaque	84	90.3
	1: plaque < 1/3 of crown	7	7.5
	2: plaque 1/3 - 2/3 of crown	2	2.2
	3: plaque > 2/3 of crown	0	0
Gingiva index	0: normal gingiva	57	61.3
	1: no bleeding on probing	0	0
	2: moderate bleeding on p.	36	38.7
	3: spontaneous bleeding	0	0
Probing depth	Mean \pm S.D. (max)		
	Mesial	2.6 \pm 1.1 mm	(5 mm)
	Buccal	2.1 \pm 0.8 mm	(4 mm)
	Distal	2.3 \pm 1.1 mm	(5 mm)
	Oral	2.4 \pm 1.0 mm	(5 mm)
Width of keratinized mucosa	Mean \pm S.D.	2.7 \pm 1.4 mm	
	Range	0 - 6.0 mm	
Gingival recession	Mean \pm S.D.	0.29 \pm 0.7 mm	
	Range	0 - 4.0 mm	

Table 3: Implant follow-up parameters.

membrane removal is done at the same time as the healing abutments are connected, keeping the number of surgeries to a minimum.

It is concluded that guided bone regeneration (GBR) using the Ti-reinforced NeoGen membrane and simultaneous implant placement is a reliable and time efficient treatment in cases where bone augmentation is needed for implant placement.

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Managing membrane complications. A technique description

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This article presents the successful treatment of soft tissue complications during guided bone regeneration (GBR) in four clinical cases.

INTRODUCTION

Soft tissue complications is a relatively common event during guided bone regeneration (GBR). A recent systematic review has identified complication rates between 0 and 45% with a mean complication rate of 16.8%.¹

The most common complications are membrane exposure and acute infection. If not treated in a timely and correct manner, they can cause infection of the regeneration site and negatively affect the GBR procedure.

As reported by Lim et al.,¹ the complication rate is highly procedure related. Soft tissue management, such as achieving a stress-free wound closure, may still be the main component to avoid soft tissue complications.

If soft tissue complications occur, different membrane materials have different degree of resistance to infection. The traditional non-resorbable expanded polytetrafluoroethylene (e-PTFE) membranes required almost imme-

diately removal upon exposure, whereas dense PTFE has been shown to withstand infection better. The membranes used in this case series (NeoGen Ti-Reinforced Membrane, Neoss Ltd, Harrogate, UK) have been shown to be totally bacterial resistant after 48 hours in vitro.^{2,3}

Soft tissue complications do not automatically result in failed GBR treatments. Lim et al. reported that the majority of sites experiencing complications healed without significant impact on the GBR procedure.¹

A clinical follow-up on implants placed with simultaneous GBR using NeoGen membranes reported similar findings. The study showed that soft tissue complications occurred in 13 out of 107 membrane sites (12.1%). All thirteen complications were successfully treated and the implant survival in the study was 100%.⁴

This article presents four of these thirteen complication cases.

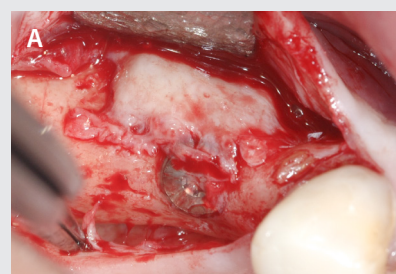
Case 1: 73 years old male patient receiving two implants in lower first premolar and first molar area with simultaneous placement of NeoGen membrane.

A partial crestal membrane exposure occurred one week after membrane placement in the premolar area. The patient was instructed to rinse with chlorhexidine.

After another 3 weeks, the membrane was removed and the site closed allowing continued submerged healing.

Six months after implant placement, at time of re-entry, good bone regeneration was observed (A) indicating that the membrane had provided crucial stability during the first month of healing.

Implants successful 1 year after loading.



A: Bone regeneration 6 months after surgery in the premolar area.

Case 2: 26 years old female patient receiving one implant in the upper lateral incisor area with simultaneous placement of NeoGen membrane.

Implant placement and GBR procedure (A-E). Infection occurred 2.5 months after membrane placement in the premolar area (F). The membrane was removed (G) and the patient was treated with antibiotics.

After another month, soft tissue was removed from the site (H) and reaugmentation was performed (I).

Upon re-entry (J-K), seven months after implant placement and 3.5 months after reaugmentation, bone regeneration around the implant was sufficient (L). A PEEK healing abutment was connected for transmucosal healing (M).

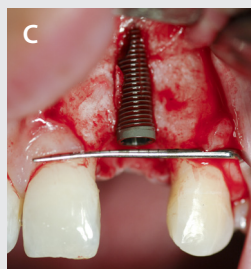
The implant was restored one month later and has been successfully in function for more than 2 years.



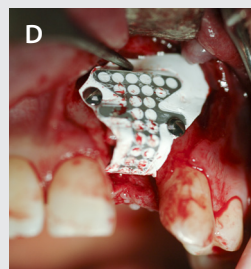
A: Very thin ridge.



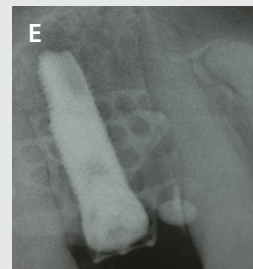
B: Neoss ProActive implant placed.



C: Large buccal dehiscence.



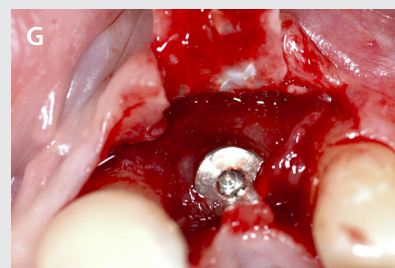
D: Site grafted and membrane placed.



E: Radiograph directly after surgery.



F: Infection 2.5 months after surgery.



G: Membrane removal 2.5 months after surgery. Fibrous tissue buccally.



H: Site reopened and fibrous tissue removed one month later.



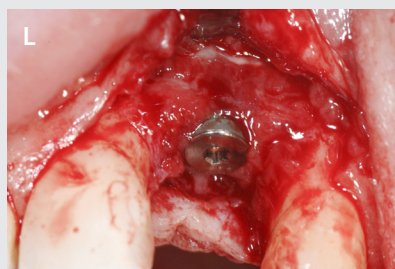
I: Reaugmentation 3.5 months after first surgery.



J: Uneventful healing after reaugmentation.



K: Membrane removal 3.5 months after reaugmentation.



L: Regenerated bone after reaugmentation procedure.



M: PEEK healing abutment connected.

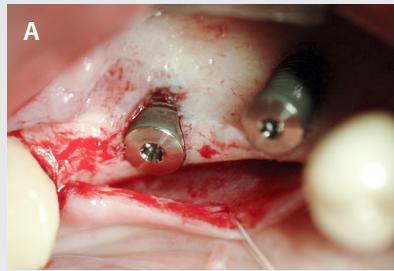
Case 3: 57 years old female patient receiving two implants in the upper molar area with simultaneous placement of NeoGen membrane.

Partial membrane exposure and pus crestal in the first molar area was discovered 3.5 months after surgery.

The site was rinsed with chlorhexidine (CHX) rinse and treated with topical CHX gel. Patient was given antibiotics and was instructed to use CHX gel three times a day.

After one week, signs of soft tissue infection were still present (B). Membrane was removed revealing regenerated bone (C).

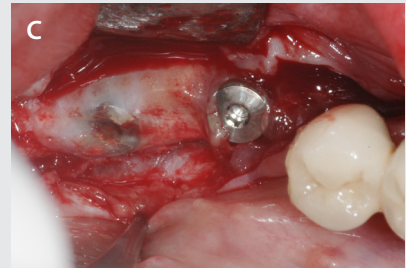
The implants were restored 1.5 months later and has been successfully in function for more than 2 years.



A: Implant placement. Buccal dehiscences before GBR procedure.



B: Infected soft tissue after one week of treating the complication.



C: Membrane removal. Bone regeneration.

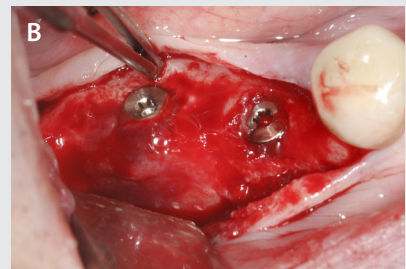
Case 4: 67 years old male patient receiving two implants in the lower molar area with simultaneous placement of NeoGen membrane.

Membrane exposure with crestal pus three weeks after surgery (A). The membrane was removed (B) and bone exostoses smoothed.

The implants were restored after another four months of healing and have been successfully in function for more than 2 years.



A: Three weeks after surgery. Membrane exposure and crestal pus on distal site.



B: Membrane removed. No signs of infection in regeneration site.

The presented cases show that soft tissue complications such as membrane exposures and local infections can be successfully treated without substantially affecting the GBR procedure outcome. The cases also show that the NeoGen membrane in certain cases can be left in place for a limited time after a complication occurs to allow for bone regeneration to continue, as long as the site is closely monitored.

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